

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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GILEAD SCIENCES, INC. and GILEAD  
SCIENCES IRELAND UC,

Plaintiffs,

v.

SAFE CHAIN SOLUTIONS, LLC; PATRICK  
BOYD; CHARLES BOYD; WORLDWIDE  
PHARMA SALES GROUP, INC. d/b/a  
PHARMASALES.COM; ADAM S. BROSIUS;  
BOULEVARD 9229 LLC; and ISHBAY  
SHUKUROV,

Defendants.  
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Case No. \_\_\_\_\_

**FILED *EX PARTE* AND UNDER SEAL  
PURSUANT TO 15 U.S.C. § 1116(d)**

**MEMORANDUM OF LAW IN SUPPORT OF  
PLAINTIFFS' MOTIONS FOR *EX PARTE* SEIZURE ORDER, TEMPORARY  
RESTRAINING ORDER, ASSET FREEZE ORDER,  
EXPEDITED DISCOVERY ORDER, AND  
ORDER TO SHOW CAUSE FOR A PRELIMINARY INJUNCTION**

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Plaintiffs Gilead Science, Inc. and Gilead Sciences Ireland UC (together, “Gilead” or “Plaintiffs”) submit this memorandum of law in support of their application seeking immediate injunctive relief against Defendants Safe Chain Solutions, LLC (“Safe Chain”), Patrick Boyd, Charles Boyd (together, “the Boyds”), Worldwide Pharma Sales Group, Inc. d/b/a/ Pharnasales.com (“Worldwide Pharma”), Adam S. Brosius (“Brosius”), Boulevard 9229 LLC (“Boulevard”), and Ishbay Shukurov (“Shukurov”) (collectively, “Defendants”). Gilead seeks (1) an *ex parte* seizure order; (2) a temporary restraining order, to be followed by a preliminary injunction; (3) an expedited discovery order; and (4) an asset freeze order.

### **INTRODUCTION**

Gilead brings this anti-counterfeiting action in an urgent effort to remove dangerous counterfeit HIV medications from the U.S. market. Gilead has received a series of complaints from patients and pharmacies in New York City and across the United States about bottles of Gilead drugs that do not contain the HIV medication listed on the label, but rather different drugs entirely – most commonly, high-dose tablets of a prescription antipsychotic that can cause debilitating side effects. Gilead’s testing, confirmed by an outside lab, revealed these to be authentic Gilead bottles that had been opened and emptied, refilled with foreign tablets, and then re-sealed with replicas of Gilead’s tamper-evident seal. As a result, American patients received what appeared to be new, sealed bottles of their Gilead HIV medications, but were actually receiving completely different, unprescribed drugs. These counterfeits failed to treat or protect the patient from HIV infection, and also put the unwitting patient at risk of serious injury or death from the foreign medications’ side effects and drug interactions.

The Defendants in this action are a pharmaceutical distributor; a pharmaceutical “marketing” company acting on its behalf to traffic the counterfeits; a pharmacy unlawfully acting as a pharmaceutical distributor; and their respective principals. All of the Defendants

have sold multiple bottles of counterfeit HIV medications that Gilead has tested and confirmed to be counterfeit. But Gilead has been able to collect only a tiny sample of the Gilead HIV medications that the Defendants trafficked. Records indicate that the Defendants purchased thousands of additional bottles purporting to be Gilead drugs at impossible discounts, well below the lowest available wholesale price. An untold number of patients are at risk.

The most crucial relief Gilead seeks is an *ex parte* seizure order pursuant to the Trademark Counterfeiting Act of 1984, 15 U.S.C. § 1116(d), against the distributor Safe Chain, and its upstream counterfeit supplier Boulevard, and Boulevard's principal, Shukurov. A seizure allowing Gilead to take control of these counterfeit distributors' stock and granting Gilead access to their communications about the counterfeits is vital to Gilead's efforts to shut down this counterfeiting network and remove these dangerous counterfeit drugs from the pharmaceutical supply chain.

In addition to an *ex parte* seizure order, Gilead seeks a temporary restraining order and a preliminary injunction against all Defendants to prevent them from continuing to traffic in counterfeit Gilead HIV medication. Gilead also seeks an asset freeze to prevent Defendants from dissipating their unlawful profits. Finally, Gilead also seeks an order authorizing limited expedited discovery so that it can find others who have bought or sold counterfeit Gilead medication and remove the counterfeits from the supply chain.

The public health risk posed by the Defendants' counterfeit HIV medications is dire. The Gilead medications at issue are therapies for patients living with HIV, as well as pre-exposure prophylactic (PrEP) medication for persons who are at risk of HIV infection. Gilead HIV medication needs to be taken daily to maintain its efficacy. Missing even a few days of HIV treatment can lead to a significant increase in a patient's viral load, and viral rebound can have

severe consequences. Patients who are at risk of HIV infection and are taking PrEP will falsely believe that they are protected against the virus after taking the Defendants' counterfeits. The counterfeit bottles of HIV medications are not only adulterated and tampered with: they ***contain entirely different drugs that were not prescribed by the patients' doctors***. The most common contents of the counterfeits are a high-dose antipsychotic with severe side effects, including an extreme sedated or drowsy state. One patient reported to Gilead not being able to "speak or walk" after taking the drug in a counterfeit bottle of HIV medications sold by Defendants. Patients taking the counterfeit products received no warning of these side effects, exposing themselves and others to extreme danger should they unwittingly proceed to drive a car, operate machinery, hold a baby, or engage in another activity in which it is unsafe to be sedated and impaired.

Defendant Safe Chain is the primary known distributor of these counterfeit drugs. Safe Chain purchased counterfeits from a stable of recently opened, unregistered, fly-by-night suppliers who sold Gilead medications at a discount that no legitimate distributor could offer, accompanied with obviously falsified pedigrees. When Gilead began receiving reports of counterfeit HIV medications that Safe Chain had sold to pharmacies, Gilead initially reached out to Safe Chain on the assumption that it was also an innocent victim. But while Gilead was attempting to engage Safe Chain in a good-faith effort to eradicate the counterfeits, Safe Chain dragged its feet and stalled for time, concealed crucial information, and continued to buy ***thousands*** more bottles of Gilead HIV medications from the ***same*** counterfeit suppliers, all of them accompanied by fraudulent pedigrees. Gilead also recently learned that Safe Chain has been intentionally providing false information to Gilead throughout Gilead's investigation. For example, when Safe Chain sent Gilead the pedigree for a confirmed counterfeit bottle, Safe

Chain did *not* forward the pedigree it had provided to its pharmacy customer at the time of sale. Rather, Safe Chain secretly created a *new* pedigree with a less obviously fraudulent transaction history and sent that to Gilead instead.

Defendant Worldwide Pharma conspired with Safe Chain to buy, market, and sell the counterfeits. Worldwide Pharma is owned and operated by Defendant Brosius, who is under federal indictment on multiple counts of health care fraud. Brosius founded Worldwide Pharma immediately after being removed from the board of the pharmacy that he used to orchestrate a multimillion-dollar prescription drug scam. Worldwide Pharma was involved in every step of Safe Chain's counterfeiting: it was listed as the primary contact for its counterfeit suppliers, and it marketed and sold the counterfeits to Safe Chain's pharmacy customers.

Finally, Defendant Boulevard, located in Rego Park, Queens, supplied Safe Chain with counterfeits and created fraudulent pedigrees for them. Boulevard is licensed as a retail pharmacy, not a pharmaceutical distributor, but it sold counterfeit Gilead HIV medications across state lines to Safe Chain. A classic fly-by-night counterfeiter, Boulevard operated out of a small office space in a condominium building with no Internet or social media presence, and no registration with the FDA. Boulevard's owner, Defendant Shukurov, owns another pharmacy involved in a health care fraud scheme, and has been identified as an unindicted co-conspirator in an ongoing federal criminal prosecution. Gilead recently served a subpoena on Boulevard in connection with another litigation involving diverted Gilead HIV medication, and Boulevard simply ignored it.

Gilead has for the past several months been attempting to address the counterfeiting problem without resorting to the courts. Gilead has been investigating and testing the counterfeit products that were brought to its attention, coordinating and cooperating with the FDA's Office



of Criminal Investigation, interviewing pharmacies and wholesalers, testing samples, sending out pharmacy alerts, and attempting in vain to convince Safe Chain to meaningfully cooperate.

Gilead now brings this action on an urgent, *ex parte* basis, because these self-help measures have proved inadequate to protect the public from the dangerous counterfeit HIV medications that is circulating in the United States. After spending months obtaining only partial and delayed cooperation from Safe Chain, Gilead recently discovered that Safe Chain was blatantly lying to Gilead about its source of Gilead's HIV medication. Safe Chain represented that going forward, Safe Chain was buying its Gilead products from a new supplier (which it did not identify), and that the supplier sourced its Gilead drugs directly from Cesar Castillo LLC ("Cesar Castillo"), a Gilead authorized distributor. Safe Chain further represented that it had contacted Cesar Castillo, confirmed that Cesar Castillo in fact sold Gilead products to this new supplier, and even confirmed the supplier's account number in Cesar Castillo's system.

Safe Chain's representations turned out to be blatant lies. Through a cooperating pharmacy, Gilead recently obtained pedigree documents that identified Safe Chain's new supplier of Gilead products: Synergy Group Wholesalers LLC ("Synergy"). The pedigree did state that Synergy purchased Gilead medication directly from Cesar Castillo – but the pedigree is fake. Gilead has never sold the drugs listed on the pedigree to Cesar Castillo. Moreover, as set forth in the attached declaration from Cesar Castillo, Synergy has never been a customer of Cesar Castillo, and, contrary to Safe Chain's representations, Safe Chain never contacted Cesar Castillo regarding Synergy or any other wholesaler.

Courts routinely grant *ex parte* seizure orders, temporary restraining orders, and asset freezes against counterfeiters. But this is not a routine counterfeiting case. At issue are not counterfeit handbags, T-shirts, or watches: Defendants are peddling counterfeit HIV drugs that

pose serious and ongoing physical danger to the American public. There is no willfulness or intent requirement to establish liability for selling counterfeits. But the evidence Gilead has been able to collect through its independent investigation demonstrates that the Defendants are, in fact, knowing and willful counterfeiters who are intentionally sacrificing patients' health in order to make a profit – and who will continue doing so until this Court stops them. Gilead respectfully urges the Court to issue a seizure order, along with the other relief it requests in this motion, so that Gilead can put an immediate stop to Defendants' counterfeiting and track down the counterfeit drugs that are flowing through U.S. commerce.

## **STATEMENT OF FACTS**

### **I. GILEAD'S HIV MEDICATIONS**

#### **A. Gilead's Trademarks**

Gilead is the owner of several different registered, well-established, and famous trademarks that appear on the packaging of genuine Gilead HIV medications. Those trademarks and proof of their registration are set forth as Exhibit 1 of the Declaration of Gretchen Stroud, dated July 20, 2021 ("Stroud Decl."). Ms. Stroud's declaration also sets forth evidence of the marks' famousness and use.

#### **B. Gilead's HIV Medications**

The Gilead HIV medications at issue are groundbreaking treatments that have transformed the lives of patients infected with HIV and persons who are at high risk of HIV infection. So far, Gilead has received samples of, tested, and confirmed counterfeits of two Gilead HIV medications: BIKTARVY® and DESCOVY®.

BIKTARVY® is a complete, one-pill, once-a-day prescription medication used to treat HIV. Decl. of Joel Gallant, dated July 21, 2021 ("Gallant Decl.") ¶ 8. It has a demonstrated long-term efficacy and safety profile, few drug interactions and side effects, and a high barrier to

developing drug resistance. *Id.* ¶ 9. Although BIKTARVY® does not cure HIV, when taken every day as prescribed, it can lower the amount of virus in a patient’s blood to undetectable levels. *Id.* ¶ 10.

DESCOVY® is approved by the FDA for pre-exposure prophylactic (PrEP) HIV therapy. *Id.* ¶ 12. When used for PrEP, DESCOVY® is prescribed to individuals who are at risk for HIV infection. *Id.* Taken once a day regularly as prescribed, DESCOVY® is highly effective in preventing HIV-1 infection. *Id.* ¶¶ 12, 13.

As discussed in further detail below, the counterfeiters sold thousands of bottles of other Gilead HIV medications that, like the confirmed counterfeits, were sold with fraudulent pedigrees. Those other Gilead drugs also treat HIV infection and/or are taken for PrEP therapy.

## **II. THE DEFENDANTS’ COUNTERFEIT HIV MEDICATIONS AND FRAUDULENT PEDIGREES**

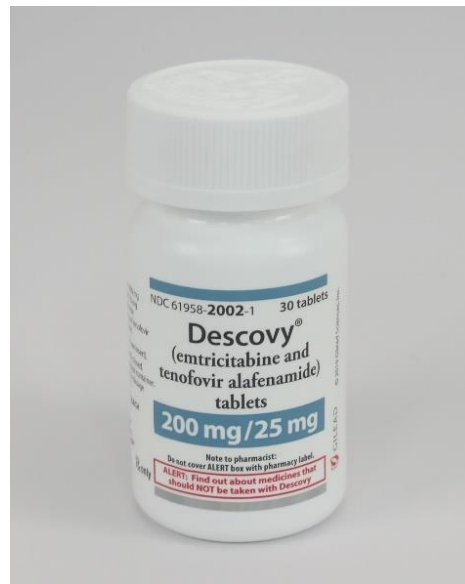
### **A. Gilead’s Testing of the Counterfeits**

In late 2020, Gilead received what would be one of several patient complaints about bottles of counterfeit Gilead HIV treatments, containing foreign medication, that a pharmacy had purchased from Safe Chain. Decl. of Susmitha Sunkara, dated July 20, 2021 (“Sunkara Decl.”) ¶ 49. In the ensuing months, Gilead received reports of eight patient and pharmacy complaints about Gilead HIV medications sold by Safe Chain that had foreign tablets inside. *Id.* ¶ 4. For most of these reports, Gilead obtained samples of the counterfeit medication. *Id.* ¶ 5.

Gilead’s in-house scientists in its quality and packaging departments examined the suspect bottles, made inquiries of the manufacturing and packaging plants responsible for each bottle, and sent each bottle to an outside lab for further analysis. *Id.* ¶¶ 5-6. Gilead confirmed that each of the eight bottles contained foreign drugs – *i.e.*, drugs that were different than what appeared on the label. *Id.* One of the bottles contained an over-the-counter analgesic; one

contained NORVIR<sup>®</sup>, an antiviral manufactured by AbbVie; three contained quetiapine, an antipsychotic that is available as a generic but is also sold under the brand name SEROQUEL XR<sup>®</sup>; and the remainder were filled with different (and older) Gilead HIV medications: one each of STRIBILD<sup>®</sup>, VIREAD<sup>®</sup>, and GENVOYA<sup>®</sup>. *Id.* ¶¶ 16, 22, 28, 34, 39, 44, 49, 54.

These foreign tablets appeared to be in authentic Gilead bottles, bearing authentic labels. *Id.* ¶¶ 19, 25, 31, 36, 41, 46, 51, 56. BIKTARVY<sup>®</sup> and DESCOVY<sup>®</sup> are both FDA-approved for sale only inside of Gilead's original bottles; unlike many other prescription drugs, they cannot be lawfully dispensed in generic pharmacy bottles. *Id.* ¶ 14.



Gilead's original bottles contain a desiccant, and the mouths of the bottle are heat-sealed with a tamper-evident foil seal. *Id.* ¶ 15.



Gilead's authentic foil seals are applied in such a way that the foil is fused into the grooves for the screw-on cap, making it nearly impossible to fully remove all traces of the original seal. *Id.* The tested bottles of BIKTARVY® had remnants of Gilead's original foil seal, as well as a different, replica seal that had been applied over it. *Id.* ¶¶ 19, 25, 36, 41, 46, 51. The outside laboratory confirmed that the secondary seal was not genuine and that it was affixed with a different kind of adhesive than the genuine seal. *Id.* The counterfeiters appear to have taken authentic BIKTARVY® bottles; emptied them of their contents (or obtained them empty); inserted into them foreign drugs; and applied a replica seal to give the appearance of a new, unopened bottle.

The counterfeit bottle of DESCOVY® contained a different Gilead drug, VIREAD®. *Id.* ¶ 54. VIREAD® is an older Gilead product that is off-patent and available as a generic. In this case, the counterfeit bottle was not a genuine DESCOVY® bottle, but rather appeared to be a VIREAD® bottle with a DESCOVY® label affixed to it. *See id.* ¶ 56. Thus, the counterfeit DESCOVY® appears to have been an authentic, sealed bottle of VIREAD® that had its label removed and a label for DESCOVY® affixed in its place. *See id.*

For each of the confirmed counterfeit bottles, Gilead contacted the responsible manufacturing and packaging plants. Gilead confirmed that it was impossible for the insertion of foreign tablets to have occurred at either the manufacturing or packaging stage. *Id.* ¶¶ 7-9, 20, 21, 26, 27, 32, 33, 37, 38, 42, 43, 47, 48, 52, 53, 57, 58. Gilead's manufacturing and packaging plants did not have the foreign medication on the premises during the creation or bottling of that lot. *Id.* None of the lots at issue had any anomalies or issues noted during the manufacturing or bottling process. *Id.* And the lines have rigorous controls to prevent foreign contamination, including sealed workspaces with gowned workers; visual inspection of a large sample of each

lot; and weighing of each bottle before allowing it to leave the line. *Id.* The difference in weight between, for example, BIKTARVY® and other Gilead medications would have triggered the weighing systems and prevented the bottles from leaving the BIKTARVY® line. *Id.*

Gilead does not currently know how the counterfeiters are obtaining authentic bottles of Gilead HIV medications to manufacture their counterfeits. That will be one area of focus of the requested expedited discovery. The most likely explanation is that the counterfeiters are collecting them from patients or pharmacies. In a separate action pending before the U.S. District Court for the Southern District of Florida (the “Florida Action”),<sup>1</sup> Gilead has uncovered a vast fraudulent scheme to illegally divert Gilead’s HIV medication, which includes unscrupulous pharmacists who violate FDA regulations by removing Gilead’s HIV medications from their original Gilead bottles and dispensing them in generic pharmacy vials. This unlawful practice creates a potential supply of empty, original Gilead bottles for use in counterfeiting.

#### **B. The Counterfeit HIV Medications Pose a Severe Risk to Public Health**

Both BIKTARVY® and DESCOVY® come in thirty-tablet bottles, representing a one-month supply of the drug. Gallant Decl. ¶ 14. For patients treating HIV infection, it is important that the patient take the Gilead medication once a day, every day. *Id.* ¶ 15. If a patient skips doses for even a short period of time, the patient faces the risk that the patient’s viral load – *i.e.*, the amount of HIV in their blood – will increase. *Id.* Viral rebound can have severe consequences: over time, it can weaken the patient’s immune system and increase the possibility of infections; it can result in progression of the disease and lead to the development of AIDS; and it can make patients more likely to infect their sexual partners. *Id.* ¶ 16.

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<sup>1</sup> *Gilead Sciences, Inc., et al. v. AJC Medical Group, Inc., et al.*, No. 20-cv-24523 (S.D. Fla.).

Patients taking DESCOVY for PrEP<sup>®</sup> must also take the medication regularly to receive the prophylactic benefits of the drug. *Id.* ¶ 18. DESCOVY for PrEP<sup>®</sup> is recommended only for individuals at risk for HIV infection. *Id.* ¶ 12. Patients who unknowingly discontinue their DESCOVY<sup>®</sup> treatment because they have received counterfeit medication put themselves at high risk for contracting HIV while still believing they are being protected from infection. *Id.* ¶ 18.

Finally, the foreign drugs inside the counterfeits pose a host of serious risks to patients who have never been prescribed that medication and have no idea they are taking it. The most common foreign drug in recovered counterfeits is the antipsychotic quetiapine, marketed under the brand name SEROQUEL XR<sup>®</sup>. Quetiapine is a prescription antipsychotic medication with a number of known serious side effects that require vigilant medical supervision. *Id.* ¶¶ 22-23. Quetiapine also poses serious dangers to patients with common health conditions, such as high blood pressure, diabetes, and low white blood cell counts, whose conditions must be closely monitored while taking quetiapine. *Id.*

Quetiapine very commonly causes a strong sedated state or drowsiness. *Id.* Patients are also susceptible to fainting when taking quetiapine. *Id.* As noted on the FDA labelling for the drug, these effects are especially acute for first-time users of the drugs. *Id.* One patient who unknowingly took SEROQUEL XR<sup>®</sup> when she received a counterfeit bottle of BIKTARVY<sup>®</sup> reported that she could not speak or walk afterwards. Sunkara Decl. ¶ 23. Patients who are prescribed quetiapine are warned against driving or operating machinery. Gallant Decl. ¶ 22.

In part because of this strong sedative effect, the FDA labelling for quetiapine recommends that new patients be given a small dose – 50 milligrams a day for many conditions – that can be increased over time as the patient’s physician tracks the side effects and monitors

the patient’s reaction to the drug. *Id.* ¶ 23. The counterfeit Gilead HIV medication contained 300-milligram tablets of quetiapine. *Id.*

Of course, patients who ingest quetiapine from a counterfeit bottle of HIV medication have no idea that they are taking a medication with these side effects and receive no warning of the possible consequences of doing so. They have no idea they are not supposed to drive, operate heavy machinery, or engage in other activities where sedation or drowsiness are dangerous, and as a result are placed in grave danger of injury or death.

### **C. Defendants’ Use of Fraudulent Pedigrees to Sell the Counterfeits**

Congress has implemented a system to crack down on pharmaceutical counterfeiting and ensure the safety of patients by requiring the tracking of every sale of every prescription drug in the country. The Defendants used fraudulent documentation to bypass those protections and put their counterfeits into the hands of U.S. pharmacies and patients.

#### **1. The DSCSA and Pedigrees**

In 2013, Congress enacted the Drug Supply Chain Security Act (“DSCSA”), 21 U.S.C. §§ 360eee *et seq.* The DSCSA establishes a regulatory regime for the tracking and verification of every sale or transfer of a prescription drug in the United States. The central feature of the DSCSA is the requirement that every sale or transfer of a prescription drug must be accompanied with a record showing the chain of all sales or transfers of that drug, going back to the manufacturer. *Id.* § 360eee-1(b)(1). In the industry, this is known as the drug’s “pedigree,” and is also referred to as the drug’s DSCSA documentation or “T3” documentation – standing for the three “Ts” of transaction information, transaction history, and transaction statement that must be included on the pedigree. The “transaction statement” aspect of a pedigree requires the wholesaler or distributor selling a prescription drug to verify, among other things, that it is not knowingly shipping a “suspect or illegitimate product”; that it “received the product from a



person that is authorized as required under the Drug Supply Chain Security Act”; and that it “did not knowingly provide false transaction information” to its purchaser. 28 U.S.C. § 360eee(27); *id.* § 360eee-1(a)(2)(A). On its website, the FDA states that the purpose of these tracing requirements is to “help protect consumers from exposure to drugs that may be counterfeit.”<sup>2</sup>

## **2. The Pedigrees from the Counterfeit Distributors Are All Fraudulent**

A counterfeit product cannot have a legitimate pedigree. It is not surprising, then, that all of the pedigrees that accompanied the tested and confirmed counterfeits are fake. Sunkara Decl. ¶¶ 17, 24, 30, 35, 40, 45, 50, 55; Decl. of Sidnie Bienz, dated July 20, 2021 (“Bienz Decl.”) ¶¶ 9, 14, 19, 25, 31, 37. Beyond the confirmed counterfeits, Gilead has received copies of pedigrees for thousands of additional bottles that Safe Chain purchased from the same suppliers who sold the confirmed counterfeits. Those pedigrees are also fake. In the United States, Gilead sells its medications only to sixteen Gilead authorized distributors. Sunkara Decl. ¶ 10. Yet some of the Safe Chain pedigrees falsely listed an initial sale from Gilead to a distributor other than a Gilead authorized distributor.

Some of the other fraudulent pedigrees did list sales from Gilead to an authorized distributor, and from that authorized distributor to the counterfeit supplier. Yet the authorized distributors listed on the pedigrees have confirmed that the pedigrees are false: the authorized distributor never sold any products to the counterfeit supplier. *See* Decl. of Luis Vazquez, dated July 20, 2021 (“Vazquez Decl.”) ¶ 14; Decl. of Bruce Gundy, dated July 21, 2021 (“Gundy Decl.”) ¶ 4. Moreover, Gilead has confirmed that it never sold the lot numbers listed on most

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<sup>2</sup> FDA, *Drug Supply Chain Security Act (DSCSA)*, <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>.

pedigrees to that particular authorized distributor, or that the pedigrees claimed that Gilead sold a particular lot number months before the lot was released by Gilead. *See, e.g.*, Sunkara Decl.

¶¶ 17, 35, 40, 50.

### **III. SAFE CHAIN IS TOLD IT HAS SOLD COUNTERFEIT GILEAD MEDICATION AND KEEPS SELLING THEM**

Safe Chain has repeatedly been informed that it purchased and sold counterfeit Gilead HIV medications containing foreign drugs. Yet instead of making open and transparent efforts to remove these potentially deadly counterfeits from the market, Safe Chain has repeatedly refused to provide requested information, concealed reported counterfeits, lied to Gilead, and, worst of all, *kept buying* thousands of additional bottles of supposed Gilead HIV medications from the *same* counterfeit suppliers, all of them with fraudulent pedigrees – *after* being informed that these suppliers had sold dangerous counterfeit products.

#### **A. Safe Chain Contacts Gilead About Counterfeits but Refuses to Cooperate with Gilead’s Investigation**

In August 2020, one of Safe Chain’s customers, White Cross Pharmacy of Brawley, CA, received a complaint from a patient of a counterfeit BIKTARVY® bottle containing a generic of an over-the-counter analgesic instead of the BIKTARVY®. Sunkara Decl. ¶ 49. White Cross reported the incident to Gilead and shipped a sample of the counterfeit product to Gilead. *Id.* Subsequently, Safe Chain contacted Gilead to inform Gilead about the counterfeit. Decl. of Geoffrey Potter, dated July 21, 2021 (“Potter Decl.”) Ex. 7. On September 11, 2020, Gilead asked Safe Chain to identify who had supplied this counterfeit, but Safe Chain refused to provide the requested information. *Id.*

On October 5, 2020, Safe Chain contacted Gilead again, this time with a cryptic request to verify the expiration date on a bottle of BIKTARVY®. Potter Decl. Ex. 8. Gilead responded by asking Safe Chain why it was inquiring about the product and requesting more information

and photographs of the bottle. *Id.* Safe Chain did not provide photographs or otherwise explain what had prompted the inquiry, but it did send a purported pedigree document for the bottle. The pedigree in question claimed an initial sale of BIKTARVY® from Gilead to a “drug co-op,” not an authorized distributor; the pedigree was false. *Id.* Accordingly, Gilead responded on October 9, 2020 that the transaction history was incorrect, and that the drugs on the pedigree “should be treated as an illegitimate product and quarantined and should be reported to the FDA.” *Id.* Safe Chain did not respond to Gilead’s e-mail.

**B. Gilead Notifies Safe Chain of Confirmed Counterfeits and Is Met with Obfuscation and Lies**

Meanwhile, Gilead continued to investigate the complaint about counterfeit BIKTARVY® from White Cross Pharmacy, confirming through lab testing that the bottle was counterfeit. *See* Sunkara Decl. ¶¶ 49-53; Bienz Decl. ¶¶ 9-12. White Cross provided Gilead with an invoice indicating that the product had been purchased from Safe Chain. Having heard nothing further from Safe Chain, Gilead sent Safe Chain a letter on November 23, 2020, asking for an update on the October complaint and notifying Safe Chain of the counterfeit BIKTARVY® that White Cross Pharmacy had purchased from Safe Chain. Potter Decl. Ex. 9. Gilead asked Safe Chain to confirm that it had in fact sold the drug to White Cross and, if so, for Safe Chain to provide all information, correspondence, and documentation concerning its purchase of the counterfeit. *Id.*

**1. Safe Chain Continues to Refuse to Identify Its Counterfeit Supplier**

Safe Chain responded to Gilead through counsel on December 7, 2020. Potter Decl. Ex. 10. Safe Chain confirmed that it had sold Gilead medication to White Cross and said it would quarantine its remaining stock with that lot number. But Safe Chain did not provide any of the requested documentation – not even the pedigree it was required to maintain by law – and

continued to refuse to identify its counterfeit supplier. Instead, Safe Chain stated only that it “can assure you we are purchasing from an authorized trading partner.”<sup>3</sup> *Id.*

Gilead responded on December 10, 2020 that Safe Chain’s response was “wholly inadequate” and again demanded that it identify its supplier of the counterfeit so Gilead could “determine how this illegitimate product made its way into the supply chain.” Potter Decl. Ex.

11. Safe Chain’s outside counsel responded by email on December 11, 2020, saying they would follow up with their client and “we will get back to you shortly.” Potter Decl. Ex. 12. Safe Chain failed to do so. Despite multiple follow-up requests from Gilead, by early February 2021, Safe Chain had still not responded.

## **2. Gilead Learns that Safe Chain Had Concealed an Earlier Reported Counterfeit Bottle of BIKTARVY®**

On February 12, 2021, Safe Chain wrote separately to inform Gilead of another complaint of a counterfeit bottle of BIKTARVY® from a different pharmacy customer, The Medicine Shoppe. Potter Decl. Ex. 13. In its letter, Safe Chain disclosed that its supplier for that counterfeit was Gentek LLC (“Gentek”). *Id.*

Gilead promptly interviewed The Medicine Shoppe. Sunkara Decl. ¶ 34. During the course of that interview, The Medicine Shoppe said that it had previously received another counterfeit bottle of BIKTARVY® from Safe Chain that had contained SEROQUEL XR®, the antipsychotic medication with severe side effects. *Id.* ¶ 16. The Medicine Shoppe stated that it had informed Safe Chain of the counterfeit in early October 2020 and returned the bottle to Safe Chain, but Safe Chain had never gotten back to them. *Id.*

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<sup>3</sup> Even this vague “assurance” from Safe Chain was knowingly false. As described below, all of Safe Chain’s counterfeit suppliers lacked proper licensure and were not registered with the FDA, and thus were not “authorized trading partners” under DSCSA.

Gilead immediately told Safe Chain what The Medicine Shoppe had disclosed, and asked for all information concerning this earlier counterfeit report. Potter Decl. Ex. 14. Safe Chain, through its outside counsel, responded on February 22, 2021, claiming that it had already disclosed the October 2020 counterfeiting report to Gilead. Potter Decl. Ex. 15. That was untrue. As Gilead stated in response, it had no record of such a communication with Safe Chain; the only October 2020 communication with Safe Chain that Gilead was aware of was the cryptic inquiry described above, which involved a different lot number of BIKTARVY®. Gilead demanded that Safe Chain immediately substantiate its claim that it had reported the October 2020 Medicine Shoppe incident to Gilead. Potter Decl. Ex. 16. Gilead later repeated that demand. Potter Decl. Ex. 17. Safe Chain never substantiated its assertion.

In fact, Gilead recently learned that Safe Chain actively prevented Gilead from finding out about the October 2020 counterfeit report. The Medicine Shoppe recently provided Gilead copies of its correspondence with Safe Chain. On November 16, 2020, Safe Chain's Director of Compliance wrote an email asking The Medicine Shoppe not to report the October counterfeit complaint to Gilead or provide Gilead the counterfeit bottle. Instead, Safe Chain asked the Medicine Shoppe to "return[] it to us, and then let us send it back." Potter Decl. Ex. 18. Safe Chain did not report the incident to Gilead or return the counterfeit to Gilead for testing. Safe Chain said nothing to Gilead about the October 2020 counterfeit until after Gilead learned of it from Medicine Shoppe.

**C. Safe Chain Finally Sends Pedigrees to Gilead, but They Are New Fake Pedigrees that Safe Chain Just Created**

By the time of its February 22 letter to Gilead, Safe Chain knew that Gilead was aware of both counterfeits it sold to The Medicine Shoppe, and so Safe Chain knew that it could no longer conceal the issue. Accordingly, Safe Chain enclosed with the letter the pedigree for the

counterfeit that had been reported to Safe Chain (but not to Gilead) in October 2020. Sunkara Decl. Ex. 1. This pedigree showed that Safe Chain purchased the October 2020 counterfeit from Gentek – the same supplier from whom Safe Chain purchased the February 2021 counterfeit. *See* Sunkara Decl. Ex. 4. Safe Chain finally provided a sample of the counterfeit bottle to Gilead, which Gilead tested and confirmed to be counterfeit. Sunkara Decl. ¶¶ 35-36; Bienz Decl. ¶¶ 19-23.

In the February 22 letter, Safe Chain also finally responded to Gilead’s request in its November 23 letter for Safe Chain’s source of the BIKTARVY® it sold to White Cross Pharmacy (which Safe Chain had previously ignored) and provided the pedigree document. That pedigree, which Gilead had first requested more than five months earlier, revealed that Safe Chain had also purchased *that* counterfeit from Gentek. Sunkara Decl. Ex. 7.

Gilead has also recently obtained a copy of one of these pedigrees directly from Safe Chain’s customer, The Medicine Shoppe. The pedigree that Safe Chain provide the pharmacy at the time of sale does *not* match the pedigree for the same counterfeit bottle that Safe Chain subsequently provided to Gilead on February 22. Before sending it to Gilead, Safe Chain deliberately altered the original pedigree to include an additional fraudulent transaction: a purported sale from Gilead to Drogueria Betances (“Betances”), a Gilead authorized distributor. The metadata of the PDF file shows that Safe Chain created that new, altered pedigree on February 19, just three days before sending it to Gilead.<sup>4</sup>

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<sup>4</sup> The metadata for the original pedigree shows it was created on the day Safe Chain sold the bottles to The Medicine Shoppe, which confirms it was the pedigree that Safe Chain created in the normal course of business.

**Pedigree that Safe Chain sent to pharmacy**

SAFE CHAIN SOLUTIONS, LLC  
**Drug Supply Chain Security Act Document** Doc# 0000019202

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: 01140811 Document Type: Invoice Reference Date: 01/08/21
Lot Number	Quantity	Unique Serial #	
6400505A	3		
CDGXBA	1		
CCZCFA	1		

**(TH) Transaction History**

Manufacturer's Name: GILEAD SCIENCES  
 Manufacturer's information:

<b>SOLD TO:</b> Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref : 01/07/21 PO#01211389	<b>SHIPPED TO:</b> Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 01/08/21 RC#016349
<b>SOLD TO:</b> Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#01211389	<b>SHIPPED TO:</b> Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
<b>SOLD TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 01S36758001	<b>SHIPPED TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01S36758001
<b>SOLD TO:</b> Name: Address: Date Purchased & Ref :	<b>SHIPPED TO:</b> Name: Address: Date Received & Ref :
<b>SOLD TO:</b> Name: Address: Date Purchased & Ref :	<b>SHIPPED TO:</b> Name: Address: Date Received & Ref :

**Pedigree that Safe Chain sent to Gilead**

SAFE CHAIN SOLUTIONS, LLC  
**Drug Supply Chain Security Act Document** Doc# 0000019202

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: 01140811 Document Type: Invoice Reference Date: 01/08/21
Lot Number	Quantity	Unique Serial #	
6400505A	3		
CDGXBA	1		
CCZCFA	1		

**(TH) Transaction History**

Manufacturer's Name: GILEAD SCIENCES, INC  
 Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

<b>SOLD TO:</b> Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Purchased & Ref : 10/05/20 85160	<b>SHIPPED TO:</b> Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Received & Ref : 10/05/20 85160
<b>SOLD TO:</b> Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref : 10/06/20 2719	<b>SHIPPED TO:</b> Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 10/06/20 2719
<b>SOLD TO:</b> Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#01211389	<b>SHIPPED TO:</b> Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
<b>SOLD TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 01S36758001	<b>SHIPPED TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01S36758001
<b>SOLD TO:</b> Name: Address: Date Purchased & Ref :	<b>SHIPPED TO:</b> Name: Address: Date Received & Ref :

Potter Decl. Ex. 48; Sunkara Decl. Ex. 4.

The reason Safe Chain altered the pedigree before sending it to Gilead is manifest. Safe Chain's original pedigree claimed that Gilead sold the counterfeit bottle directly to Gentek. Safe Chain knew that was obviously false: Gentek is not a Gilead authorized distributor, and Gilead would immediately know that purported sale to be fraudulent.<sup>5</sup> The new, altered pedigree that Safe Chain generated to send to Gilead added a new link in the sales chain: a purported initial sale from Gilead to an authorized distributor. That purported initial sale never occurred, and so the altered pedigree is still fraudulent, but it was no longer obviously so on its face.

<sup>5</sup> Moreover, the original pedigree sent to the pharmacy was missing required information about that purported original sale to Gentek: the manufacturer's address, initial purchase and receipt date, and reference number.

**D. Safe Chain Buys Thousands More Gilead Products from Gentek While Concealing from Gilead that Gentek Is Its Counterfeit Supplier**

During the time it was concealing the October 2020 counterfeit report and refusing to identify its supplier of counterfeits to Gilead, Safe Chain continued to buy tens of millions of dollars' worth of Gilead medication from the counterfeiter Gentek. Specifically, from November 2020 – *i.e.*, *after* receiving notice from White Cross Pharmacy in August 2020 and from The Medicine Shoppe in October 2020 that the BIKTARVY® supplied by Gentek was counterfeit – through January 2021, Safe Chain purchased 8,470 more bottles of Gilead medication from Gentek for over \$20 million, including over 3,400 bottles of BIKTARVY® for over \$9.5 million. Potter Decl. Ex. 19. Safe Chain purchased these thousands of bottles knowing that Gentek was selling counterfeit Gilead products with foreign medication in the bottles.

**E. Gilead Learns of Numerous Additional Counterfeits Sold by Safe Chain, Including from Previously Unknown Counterfeit Suppliers**

After responding to Safe Chain's February 22, 2021 letter with a demand for more information, Gilead did not hear from Safe Chain for over a month. On March 16, 2021, Gilead distributed to pharmacies nationwide a warning letter about the counterfeits of Gilead's HIV medications that had been sold by Gentek and Safe Chain. Potter Decl. Ex. 20.

On March 23, 2021, Gilead, through outside counsel, wrote a lengthy letter to Safe Chain detailing two new complaints from pharmacies – one in New York City and the other in Washington D.C. – about counterfeit bottles of BIKTARVY® and DESCOVY® that the pharmacies had purchased from Safe Chain. Potter Decl. Ex. 21. The pharmacy in Washington D.C. provided the pedigree for the counterfeit bottle of DESCOVY®, which indicated that Safe Chain had purchased the counterfeit from Defendant Boulevard. Sunkara Decl. ¶ 55 & Ex. 8. Gilead demanded that Safe Chain quarantine all Gilead product in its inventory and provide all



documentation, including pedigrees, of all Gilead-branded medication it had purchased since 2020. Potter Decl. Ex. 21.

Safe Chain responded on March 26. Potter Decl. Ex. 22. Safe Chain refused to quarantine its Gilead product in inventory or provide documentation for all its purchases of Gilead product. *Id.* Instead, Safe Chain attempted to blame the counterfeiting on Gentek, and said it had ceased all purchases from Gentek. *Id.* Safe Chain stated it would quarantine and provide documentation concerning only Gilead product it bought from Gentek, as well as any bottles that matched the lot numbers of the counterfeits that Gilead had tested. *Id.*

On March 29, 2021, Safe Chain wrote again to disclose that on the same day it sent its previous letter, it received a report from a pharmacy customer in Washington D.C. that the pharmacy had purchased two counterfeit bottles of BIKTARVY® from Safe Chain, each with different lot numbers. Potter Decl. Ex. 23. Safe Chain attached the pedigrees for those counterfeits, which showed Safe Chain acquired one from Defendant Boulevard, and another from a Texas distributor, Mr. Unlimited LLC (“Mr. Unlimited”), who in turn had purchased it from another Texas distributor, Rapids Tex Wholesales Corp. (“Rapids Tex”). *Id.*; *see* Sunkara Decl. Exs. 5, 6. Safe Chain stated it would “temporarily ‘freeze’” its purchases from Boulevard and Mr. Unlimited and quarantine the product it received from them. Potter Decl. Ex. 23.

**F. Safe Chain Continues to Purchase from Defendant Boulevard After Learning Boulevard Falsified Pedigree**

The March 29, 2021 letter was not the first time Safe Chain had contacted Gilead about product obtained from Defendant Boulevard. Safe Chain’s cryptic October 2020 inquiry regarding expiration dates also concerned Gilead medications that Safe Chain had purchased from Boulevard. As noted above, Gilead informed Safe Chain on October 9, 2020 that the

pedigree was false and the Gilead drugs were illegitimate, but did not receive a response from Safe Chain. Potter Decl. Ex. 8.

Gilead eventually obtained samples of the two counterfeits (BIKTARVY<sup>®</sup> and DESCOVY<sup>®</sup>) that Safe Chain had purchased from Boulevard and that were reported to Gilead in March 2021. Both samples were tested and confirmed counterfeit. Sunkara Decl. ¶¶ 39-41, 54-56; Bienz Decl. ¶¶ 37-40. According to the pedigrees, Safe Chain purchased the counterfeit DESCOVY<sup>®</sup> from Boulevard on February 23, 2021, and purchased counterfeit BIKTARVY<sup>®</sup> from Boulevard on March 1, 2021. Sunkara Decl. Exs. 5, 8. Both of Safe Chain's purchases of these counterfeits from Boulevard occurred months *after* Gilead told Safe Chain in writing that Boulevard was using false pedigrees and selling illegitimate Gilead product. *See* Potter Decl. Ex. 8. Instead of cutting ties with Boulevard, Safe Chain ignored Gilead's letter and continued to buy counterfeit Gilead products from Boulevard.

**G. Safe Chain Continues to Purchase from Mr. Unlimited and Rapids Tex After Knowingly Receiving Counterfeits**

Safe Chain's March 29 letter was the first time Gilead learned that Safe Chain was buying counterfeits from Mr. Unlimited (which in turn purchased them from Rapids Tex).<sup>6</sup> Safe Chain had sold that particular counterfeit to a Washington D.C. pharmacy on March 22, and the pharmacy reported it as counterfeit on March 26. But Safe Chain knew it was buying counterfeits from Mr. Unlimited / Rapids Tex well before that.

On or before March 9, 2021, Safe Chain received what it identified as multiple counterfeit bottles of BIKTARVY<sup>®</sup> from Mr. Unlimited, who had purchased them from Rapids

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<sup>6</sup> As discussed at pp. 36-37, *infra*, Safe Chain sourced these counterfeits from Rapids Tex, but orchestrated a scheme where Mr. Unlimited was used as a "pass-through" middleman to distance Safe Chain from the counterfeiter.

Tex. Safe Chain did not quarantine those bottles, as required by the DSCSA, or report them to Gilead. Instead, Safe Chain returned the bottles to Rapids Tex for a refund. Safe Chain's co-conspirator, Defendant Brosius of Worldwide Pharma, explained in an email:

There are 3 LOTS of Biktarvy from Gilead that have proven to be bad/counterfeit. . . . our legal counsel told us we could not take/receive these lots of Biktarvy. There were 3 units on the prior invoice. Gilead and the California [Board of Pharmacy] have deemed those 3 lots as 'bad.' We explained to Rapids Tex and they understood. thanks.

Potter Decl. Ex. 24. Rapids Tex responded by announcing "we will be shipping out today another order." *Id.*

Receiving known counterfeit Gilead medication from Rapids Tex did not deter Safe Chain and Worldwide Pharma from continuing to buy over a thousand more bottles of purported Gilead medication, all with fraudulent pedigrees and at too-good-to-be true pricing, through these entities. *See* Potter Decl. Ex. 25 (invoices between March 16 and March 26, 2021, over 1,000 bottles of Gilead products). Rapids Tex's next shipments contained more counterfeit BIKTARVY® with new lot numbers – including the confirmed counterfeit BIKTARVY® that Safe Chain reported to Gilead on March 29, plus two more tested and confirmed counterfeits that were reported by a different pharmacy the next month. There are almost certainly many others.

#### **H. Safe Chain Continues to Resist Disclosure**

Throughout April 2020, Gilead made repeated efforts to obtain full disclosure from Safe Chain and to induce them to stop purchasing Gilead products from illegitimate distributors. Although Safe Chain provided some additional information to Gilead during this time – including a new report of a counterfeit product sold by Safe Chain – it continued to drag its feet and ultimately failed to provide full documentation of the counterfeits. *See generally* Potter Decl. Ex. 6. Most significantly, while Safe Chain claimed that it would no longer purchase

Gilead products from known distributors of counterfeits, it flatly refused to identify its new supplier of Gilead products and it knowingly lied to Gilead about the nature of this supplier. *Id.*

#### IV. SAFE CHAIN LIES ABOUT HAVING A NEW “LEGITIMATE” SUPPLIER

##### A. Safe Chain Tells Gilead It Has a New Supplier but Refuses to Identify the Supplier Without an Unconditional Release

On an April 20 call with Gilead’s counsel, Safe Chain’s counsel represented that Safe Chain had a new supplier for Gilead medications that purchased directly from Cesar Castillo LLC (“Cesar Castillo”), a Gilead authorized distributor. Potter Decl. Ex. 26. Gilead asked that Safe Chain provide the pedigrees for those purchases from its new supplier, but Safe Chain did not do so. *Id.*

On May 3, 2021, Gilead served subpoenas on Safe Chain, Boulevard, and Mr. Unlimited as part of the ongoing Florida Action. *See* Potter Decl. Ex. 27. The following day, Safe Chain’s counsel memorialized in a letter Safe Chain’s earlier representation that it now had a legitimate source for Gilead product:

Safe Chain has begun making purchases of Gilead-branded products from a supplier who sourced them from Cesar Castillo (Gilead’s authorized distributor). As I mentioned, **Safe Chain has contacted Cesar Castillo to verify that this supplier is not only a customer of Cesar Castillo, but also that their account number on file with Cesar Castillo matches the account number that was listed on the Cesar Castillo invoices provided by the supplier to Safe Chain substantiating the supplier’s purchase of Gilead products from Cesar Castillo.** Safe Chain is willing to provide the list of lot numbers and expiration dates for the products which Safe Chain had purchased from the supplier who sourced them from Cesar Castillo, along with the T3 reports, **provided Gilead agrees to meet the conditions below.**

Potter Decl. Ex. 28 (emphasis added).

The “conditions” that Safe Chain demanded were untenable. They included “[w]ithdrawal of the Subpoena served on May 3, 2021,” and the following:

Please provide an **acknowledgement that Safe Chain has not falsified any of the T3 Reports** previously provided to Gilead (as had been previously insinuated) **and provide a release to Safe Chain regarding its sales of Gilead-branded medications**. . . . if [Gilead] would like Safe Chain to continue voluntarily producing additional information to Gilead, it will need this protection in place. This is perhaps the most important requirement.

*Id.* (emphasis added).

Thus, Safe Chain assured Gilead that it (finally) had a legitimate source of Gilead products who purchased directly from an authorized distributor, and that Safe Chain had (finally) undertaken due diligence to confirm, directly with the authorized distributor, that its supplier was, in fact, actually sourcing from that authorized distributor. But at the same time, Safe Chain insisted that if Gilead wanted to learn who that new supplier was, Gilead would have to withdraw a federal subpoena, falsely “acknowledge” that Safe Chain had never falsified pedigrees, and, “most important[ly],” unconditionally waive all its legal rights vis-à-vis Safe Chain’s trafficking in counterfeits, including the right to seek judicial intervention to stop Safe Chain’s counterfeiting. Gilead, of course did not agree, and so Safe Chain kept the identity of its new supplier secret.<sup>7</sup>

#### **B. Gilead Learns that Safe Chain Lied About Its New Supplier Buying from a Legitimate Source**

It was unacceptable that Safe Chain, after repeatedly selling counterfeit Gilead products, refused to disclose the identity of its new supplier. Gilead has since learned, however, that Safe Chain was not only withholding this critical information: it was actively lying to Gilead. In

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<sup>7</sup> Safe Chain later responded to Gilead’s subpoena in the Florida Action by refusing to provide any documents. When Gilead’s outside litigation counsel attempted to meet and confer with Safe Chain, Safe Chain repeated the same “conditions” to the provision of any documents, including withdrawal of the subpoena and a release of claims. Potter Decl. Ex. 29.

particular, Gilead has recently discovered that the information Safe Chain did provide to Gilead about its new supplier – that the supplier had purportedly purchased directly from an authorized distributor and that Safe Chain had confirmed this with the distributor – was false.

On May 28, 2021, The Medicine Shoppe, the pharmacy customer who had received multiple counterfeits from Safe Chain, after several requests provided Gilead copies of its communications with Safe Chain, including pedigrees. Among the documents were four pedigrees for Gilead HIV medications, including BIKTARVY®, that The Medicine Shoppe received from Safe Chain on April 19, 2021. Consistent with Safe Chain’s representations to Gilead, the pedigrees did show an initial sale to Cesar Castillo, the authorized Gilead distributor. The pedigree also identified Safe Chain’s purported new mystery supplier: Synergy Wholesale Group (“Synergy”). The pedigree indicates that Synergy purchased the Gilead HIV medications from Cesar Castillo and immediately sold them to Safe Chain. Potter Decl. Ex. 30.

Gilead’s subsequent investigation revealed that those pedigrees are fraudulent, and that Safe Chain’s claim that it verified the purchases from Cesar Castillo was a lie.

SAFE CHAIN SOLUTIONS, LLC

**Drug Supply Chain Security Act Document****(TI) Transaction Information**

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30 CT 50/200/25 MG			Reference Number: IN00002958
NDC: 61958-2501-01			Document Type: INVOICE
Lot Number	Quantity	Unique Serial #	Reference Date: 04/19/2021
021349	1		

**(TH) Transaction History**

Manufacturer's Name: GILEAD SCIENCES

Manufacturer's information: 333 LAKESIDE DRIVE, FOSTER CITY, CA 94404

<b>SOLD TO:</b> <b>Name:</b> CESAR CASTILLO INC <b>Address:</b> CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 <b>Date Purchased &amp; Ref :</b> 03/09/2021 3181920	<b>SHIPPED TO:</b> <b>Name:</b> CESAR CASTILLO INC <b>Address:</b> CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 <b>Date Received &amp; Ref :</b>
<b>SOLD TO:</b> <b>Name:</b> SYNERGY WHOLESALE GROUP <b>Address:</b> 491 AMWELL RD HILLSBOROUGH, NJ 08844 <b>Date Purchased &amp; Ref :</b> 03/30/2021 0099110	<b>SHIPPED TO:</b> <b>Name:</b> SYNERGY WHOLESALE GROUP <b>Address:</b> 491 AMWELL RD HILLSBOROUGH, NJ 08844 <b>Date Received &amp; Ref :</b>
<b>SOLD TO:</b> <b>Name:</b> SAFE CHAIN SOLUTIONS <b>Address:</b> 822 CHESAPEAKE DR CAMBRIDGE, MD 21613 <b>Date Purchased &amp; Ref :</b> 4/9/2021 000094	<b>SHIPPED TO:</b> <b>Name:</b> SAFE CHAIN SOLUTIONS <b>Address:</b> 822 CHESAPEAKE DR CAMBRIDGE, MD 21613 <b>Date Received &amp; Ref :</b> 04/12/2021

Potter Decl. Ex. 30.

The pedigrees, excerpted above, are fraudulent. First, Gilead never sold the lot numbers listed on the pedigrees to Cesar Castillo. Vazquez Decl. ¶¶ 14-18. Second, as set forth in the attached declaration of Luis Vazquez, Cesar Castillo's Director of Sales, Cesar Castillo has never sold Gilead products (or any other products) to Synergy, has never heard of either Synergy or Safe Chain, and was never contacted by Safe Chain. *Id.* In fact, Cesar Castillo has never sold a Gilead product to another distributor, period: it sells only to pharmacies and to medical facilities like hospitals and clinics. *Id.* ¶ 13.

Gilead's investigation has further revealed that Synergy is a sketchy, fly-by-night operation in the same mold as Safe Chain's other counterfeit suppliers. Synergy received its pharmacy distribution license in September 2020, just months before it started selling to Safe Chain. Decl. of Hannah Coleman, dated July 21, 2021 ("Coleman Decl.") ¶ 37. It is not licensed

to sell drugs across state lines to Safe Chain's warehouses. *Id.* ¶ 38. It has no website or Internet presence. *Id.* ¶ 39.

The Medicine Shoppe's files included an additional pedigree concerning purchases of nearly 100 bottles of Gilead HIV medications, including BIKTARVY®, from Safe Chain in early March 2021. Potter Decl. Ex 31. The pedigree states that Synergy purchased the drugs directly from Gilead. That is false. Synergy is not an authorized distributor. Synergy has never bought directly from Gilead. Sunkara Decl. ¶ 12.

In sum, the recently acquired evidence from the Medicine Shoppe demonstrates that Safe Chain's supposedly new, legitimate supplier is in fact another one of Safe Chains' unlicensed, illegitimate suppliers peddling illicit drugs with fraudulent pedigrees. Even more disturbingly, the evidence demonstrates that the assurances Safe Chain offered Gilead regarding the supposed legitimacy of its new supplier were knowing lies.<sup>8</sup> Most appallingly of all, the evidence shows that Safe Chain is continuing to buy and sell HIV medications with false pedigrees, even after being notified of numerous instances of confirmed counterfeits. There is an urgent need for judicial intervention to put an end to Safe Chain's reckless and dangerous business practices.

## **V. ADDITIONAL EVIDENCE OF SAFE CHAIN'S WILLFUL COUNTERFEITING**

Safe Chain's continued intentional trafficking in dangerous counterfeit HIV medication, in the face of patient complaints and Gilead's investigation, is more than sufficient to justify the relief Gilead seeks in this motion. But even with Gilead's limited access to documents, Gilead

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<sup>8</sup> The lie was transmitted to Gilead through Safe Chain's outside counsel. Gilead has no reason to believe that Safe Chain's outside counsel knew Safe Chain was lying, but rather assumes that Safe Chain lied to its counsel as well.



had obtained a great deal of additional evidence of Safe Chain's willful counterfeiting and its fraudulent actions to cover it up. Gilead outlines that evidence below.

**A. Safe Chain Bought Gilead HIV Medications with Obviously Fraudulent Pedigrees**

Safe Chain purchased many bottles of Gilead medication from counterfeit suppliers that were accompanied by pedigrees purporting to show Gilead selling directly to a non-authorized distributor. That was a clear indication that the pedigree was fraudulent. As noted, in the United States the only distributors to which Gilead sells its prescription drugs are its U.S. authorized distributors. Sunkara Decl. ¶ 10. The list of Gilead's U.S. authorized distributors is public, posted on Gilead's website, and easily found via a Google search.<sup>9</sup> Currently, there are sixteen U.S. authorized distributors for the Gilead HIV drugs at issue. *Id.* Any pedigree that shows an initial sale to a distributor other than one of Gilead's sixteen authorized distributors is false.

The fact that Gilead sells in the United States only to its U.S. authorized distributors is common knowledge in the industry, and is a standard practice followed by other major pharmaceutical manufacturers. Safe Chain has acknowledged that it knows Gilead sells only to authorized distributors. Potter Decl. Ex. 32 ("A number of pharmaceutical companies, like Gilead Sciences, are now distributing their products through restrictive networks of 'authorized distributors.'... For Biktarvy®, for example, the authorized distributor network consist [*sic*] of exclusive deals between Gilead Sciences and less than 20 such entities throughout the entire United States.").

Despite this knowledge, Safe Chain purchased and sold bottles of Gilead HIV medications with obviously fraudulent pedigrees listing an initial sale from Gilead to a non-

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<sup>9</sup> <https://www.gilead.com/purpose/medication-access/authorized-distributors>

Gilead authorized distributor. *See, e.g.*, Potter Decl. Exs. 31, 47. Gilead has been able to acquire and test only a small number of the drugs listed on Safe Chain's many obviously fraudulent pedigrees, but has confirmed those samples to be counterfeit. There are doubtlessly many more.

**B. Safe Chain Knew It Was Purchasing at Prices That Were Inconsistent with Legitimate HIV Medication**

The price at which Gilead sells its HIV medications does not vary from authorized distributor to authorized distributor. Gilead sells its HIV medications to each of its sixteen U.S. authorized distributors at a single list price: the Wholesale Acquisition Cost, or "WAC." Sunkara Decl. ¶ 13. Any legitimate distributor of Gilead medication would therefore be expected to sell the product at some markup from the WAC. Nevertheless, Safe Chain routinely purchased supposed Gilead HIV medications at a price significantly *below* WAC – meaning that as the drug passed through multiple hands, it somehow ended up much *less* expensive than when Gilead first sold it. Potter Decl. Ex. 33 (Defendant Brosius noting that their purchase price for a Gilead drug "should be at WAC - [minus] 18%").

Safe Chain was well aware that it was buying Gilead drugs at below WAC. In fact, that is how Safe Chain advertised to pharmacies. A cooperating pharmacy provided Gilead with a marketing email from Safe Chain and Worldwide Pharma in which Safe Chain specifically advertised that its sales prices *to pharmacies* for *all* Gilead medications were below WAC. Potter Decl. Ex. 34. Because Safe Chain, like all for-profit distributors, sell products at a markup, the price at which Safe Chain purchased these Gilead medications must have been even further below WAC. This is inconsistent with legitimate product and should have, at minimum, raised red flags for Safe Chain.

**C. Safe Chain Illegally Purchased from Unlicensed, Unprofessional, and Fly-by-Night Distributors**

As noted above, Gilead has tested and confirmed to be counterfeit bottles that Safe Chain bought from three different counterfeit suppliers: Defendant Boulevard, Gentek , and, through a “pass-through” middleman, Rapids Tex. There were numerous indications that these suppliers are illegitimate businesses, yet Safe Chain repeatedly purchased Gilead medications from them and long hid their identities from Gilead.

**1. None of Safe Chain’s Counterfeit Suppliers Are Properly Licensed or Properly Registered With the FDA**

One of the DSCSA’s anti-counterfeiting measures is its requirement that those in the business of buying and selling prescription pharmaceuticals must buy only from “authorized” trading partners. 21 U.S.C. § 360eee-1(b)(3), (c)(3). Any distributor who sells a prescription drug must attest, on the pedigree accompanying the sale, that they received the drug from an “authorized” trading partner. 21 U.S.C. § 360eee(27)(a). There are two requirements for a distributor to be “authorized” under the DSCSA: (1) having valid state licensure, both from their home state and the state into which they sold the drug; and (2) having registered with and submitted an annual report to the FDA that includes a list of all the distributor’s state licensures. 21 U.S.C. § 360eee(2)(B); 21 U.S.C. § 353(e)(1)(A)(ii).

Verifying whether a distributor is “authorized” under the DSCSA takes seconds. As mandated by the statute, the FDA maintains public a database of all registered pharmaceutical wholesalers in the United States who have filed an annual report.<sup>10</sup> Anyone with an internet connection can type in a distributor’s name and immediately confirm whether the distributor has

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<sup>10</sup> <https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>.

registered with, and met its reporting requirements to, the FDA. The FDA's database also provides a list of all states in which the distributor is licensed – *i.e.*, the states into which that distributor may legally ship prescription pharmaceuticals. *See* 21 U.S.C. § 353(e)(1)(A)(ii).

None of Safe Chain's confirmed counterfeit suppliers – Boulevard, Gentek, and Rapids Tex – has ever registered with the FDA or submitted an annual report to the FDA. Coleman Decl. ¶¶ 12, 27, 33. None of them is licensed in either Maryland or Utah, the two warehouse locations where Safe Chain received the counterfeit drugs. *Id.* And the same is true of Synergy, Safe Chain's current supplier. *Id.* ¶ 38. Every time Safe Chain sold a drug that it purchased from these suppliers, it lied on the pedigrees by attesting that it "received the product from a person that is authorized as required under the Drug Supply Chain Security Act." *See* Sunkara Decl. Exs. 2-8.

## 2. Defendant Boulevard

Boulevard is Safe Chain's upstream supplier of at least two confirmed counterfeit bottles of Gilead HIV medication. Sunkara Decl. ¶¶ 40-41, 55-56. But Boulevard is *not* a pharmaceutical distributor – or at least is not licensed as such. Rather, Boulevard is licensed in New York as a retail pharmacy, and is listed as a "Pharmacy Community/Retail Pharmacy" in the National Provider Identifier database. Coleman Decl. ¶ 10. As noted above, Boulevard is not registered with the FDA as a pharmaceutical distributor and has no license to sell to Safe Chain in Maryland or Utah. *Id.* ¶ 12.

Boulevard was founded in 2019 and received its New York pharmacy licensure on November 15, 2019. *Id.* ¶ 9, 11. Although there may be earlier sales of which Gilead is unaware, Boulevard's first known sale of supposed BIKTARVY® to Safe Chain occurred on September 15, 2020 – after Boulevard had been in business for less than a year. Potter Decl. Ex. 35.

Boulevard has no website and no internet or social media presence. Coleman Decl. ¶ 13. The company's name, Boulevard 9229 LLC, is taken simply from its address: 9229 Queens Boulevard, Suite 1i, Rego Park, New York. *Id.* ¶ 14. The company has no "assumed" or "doing-business-as" names registered. *Id.* According to prior real estate listings, that address is a two-room, 400-square-foot office space in a large condominium building. *Id.* ¶ 15.

The pedigrees for the Gilead medications Safe Chain obtained from Boulevard were fabricated. For example, the first pedigree obtained by Gilead lists an initial sale to a "drug co-op" and not a Gilead authorized distributor. Potter Decl. Ex. 35. In a subsequent pedigree, Boulevard, apparently having learned to avoid this red flag, fraudulently listed an authorized Gilead distributor as the first transaction. *See, e.g.*, Sunkara Decl. Exs. 5, 8. Gilead has also confirmed that it never sold the lots of BIKTARVY® listed on the pedigree to the authorized distributor listed, as well as confirmed with the authorized distributor that it had never sold any drugs to Boulevard. Sunkara Decl. ¶¶ 40, 55.

Defendant Shukurov, Boulevard's owner and principal, is also the owner and principal of another pharmacy in New Hyde Park, New York, named 1105 JTP LLC ("JTP"). Coleman Decl. ¶ 17. According to a recent indictment from a federal grand jury sitting in this District, JTP is one of several pharmacies that was involved in a fraudulent scheme that used "emergency overrides" granted during the COVID-19 pandemic to bill insurance for extremely expensive cancer-related drugs that were never prescribed and never dispensed. *Id.* ¶ 18 & Ex. 7. Shukurov is an unindicted co-conspirator, alleged in the indictment to have accepted bribes to maintain a front while secretly allowing the orchestrators of the scheme to use his pharmacy to commit the fraud. *See id.*

### 3. Gentek

Gentek is, by volume, Safe Chain's largest known supplier of counterfeit HIV medication. *See generally* Potter Decl. Ex. 19. Gentek was formed in Connecticut in September 2019, but did not receive licensure as a pharmaceutical distributor in Connecticut until July 2020. Coleman Decl. ¶¶ 25, 26. Safe Chain began purchasing counterfeit Gilead HIV medications from Gentek at least as early as October 2020, just three months after Gentek opened its doors – and in that first month alone, purchased several hundreds of bottles of Gilead medication for millions of dollars. Potter Decl. Ex. 19.

On its invoices and pedigrees, Gentek lists its address as 45 Cedar St, Unit 3, Stamford, Connecticut. Sunkara Decl. Exs. 1, 2, 4, 7. But that is not just its business address: as stated in Gentek's annual report to the Connecticut Secretary of State, that is the *residential* address of Edel Reyes, Gentek's CEO and registered agent. Coleman Decl. ¶¶ 25, 28, 29. Indeed, 45 Cedar Street is zoned for residential use. *Id.* In other words, Gentek was run out of its principal's home.

On February 3, 2021, a pharmacy customer filed a complaint with Safe Chain that a bottle of BIKTARVY® actually had a different Gilead HIV medication inside of it. Safe Chain reported the counterfeit to its supplier, Gentek, who gave the following response:

From: EDEL REYES <sales@gentekusa.com>  
Sent: Friday, February 5, 2021 11:11 AM  
To: Charles Boyd <CharlesB@Safechain.com>  
Subject: Re: FW: Biktavry issue with a customer

GOOD MORNING  
WILL CREDIT SAFE CHAIN FOR THE PRODUCT. PLEASE GO AHEAD AND DESTROY THE PRODUCT .THATS A MIXED BATCH ERROR ON OUR AD.  
SORRY FOR ANY INCONVENIENCE.

Edel Reyes  
PRESIDENT

Potter Decl. Ex. 36. The abbreviation “AD” stands for authorized distributor. Gentek was claiming that Gilead’s authorized distributor was responsible for the wrong medicine going into the wrong bottle. But this is plainly untrue. Gilead’s authorized distributors do not bottle Gilead’s medication, and they certainly do not open the sealed bottles of medication that Gilead delivers to them. Any experienced, law-abiding pharmaceutical distributor would have immediately recognized that Mr. Reyes’ claim was absurd. Safe Chain’s president and co-owner, Defendant Charles Boyd, however, did not object to Gentek’s obviously false claim. Rather, he responded by cheerily inquiring about his refund: “Thanks Edel! Please let me know how you would like to handle the credit.” *Id.*

The pedigrees that Safe Chain received from Gentek were also error-ridden and facially invalid. Gentek’s pedigrees claimed to have purchased Gilead products from a Gilead authorized distributor in Puerto Rico. *See, e.g.*, Potter Decl. Ex. 37; Sunkara Decl. Exs. 1, 4, 7. But not one of those pedigree documents are consistent with Gilead’s records: They are fraudulent. Sunkara Decl. ¶¶ 17, 24, 35, 50. As noted above, Gilead has confirmed that the distributor in fact never sold anything to Gentek. Moreover, numerous Gentek pedigrees claim that on the *same day* the drug was delivered from Puerto Rico to Gentek in Connecticut, it was also delivered from Connecticut to Safe Chain in Maryland, which is infeasible. Potter Decl. Ex. 37.

#### **4. Rapids Tex and Mr. Unlimited**

Safe Chain’s third confirmed counterfeit supplier is Rapids Tex, located in Harris County, Texas. Rapids Tex received its drug distribution license from Texas in February 2018. Coleman Decl. ¶ 32. As with all of Safe Chain’s suppliers, Rapids Tex has never registered as a pharmaceutical wholesaler with the FDA and has no licensure to sell in Maryland or Utah, and thus is not an “authorized” distributor of prescription drugs under the DSCSA. *Id.* ¶ 33.

**a. Safe Chain’s Pass-Through Scheme to Conceal Its Purchases from the Counterfeiter Rapid Tex**

In order to facilitate its purchase of counterfeits from Rapids Tex, Safe Chain and Worldwide Pharma conspired to identify and bribe what they called a “pass-through” wholesaler: Mr. Unlimited LLC (“Mr. Unlimited”), located in Brenham, Texas. Potter Decl. Ex. 38. Mr. Unlimited is an “authorized” distributor under the DSCSA: it has been licensed in Texas as a drug distributor since 2009, maintains a current registration and files annual reports with the FDA, and has an out-of-state pharmaceutical distributor’s license in Utah. Coleman Decl. ¶¶ 34-36. Under the pass-through scam, Rapids Tex nominally sold to Mr. Unlimited, which immediately forwarded the supposed Gilead medications to Safe Chain. Rapids Tex and Mr. Unlimited then papered the “pass-through” transaction by creating, after the fact, invoices, purchase orders, and pedigrees claiming that Mr. Unlimited purchased from Rapids Tex and sold to Safe Chain.

The purpose of the pass-through scam was to use Mr. Unlimited’s licensure to “whitewash” the pedigrees. It allowed Safe Chain to claim it was buying directly from a legitimate supplier (Mr. Unlimited) when in fact it was sourcing fake Gilead medications from the unlicensed, fly-by-night counterfeiter Rapid Tex. For its participation in the scheme, Mr. Unlimited was paid a \$1000 or \$1500 kickback per order. Safe Chain listed that kickback as a separate line item on its purchase orders as “PASS THROUGH FEE.” *See, e.g.*, Potter Decl. Ex. 39.

The evidence shows that Safe Chain’s upper management orchestrated the pass-through scam with Worldwide Pharma. *See, e.g.*, Potter Decl. Ex. 40 (Mr. Unlimited telling a Safe Chain representative that an issue with the pass-through scam had been resolved after Worldwide Pharma “spoke with Safe Chain’s owner,” and instructing Safe Chain’s representative to get the



details from Worldwide Pharma); Potter Decl. Ex. 38 (Mr. Unlimited writing: “The pass-through deal was to process a PO, Invoice and Pedigree which we’re doing. No other requirements were discussed at the beginning of the deal. If there are modifications, then Marc [Smith, a Senior Strategic Procurement Specialist for Safe Chain] and Adam [Brosius, owner of Worldwide Pharma] need to be clearly aware so we can decide if this pass-through deal is still beneficial for all parties.”); Potter Decl. Ex. 41 (“MRU [*i.e.*, Mr. Unlimited] was just doing Safe Chain a favor here.”). Notably, Safe Chain’s Director of Compliance was kept in the dark about the pass-through scam. Potter Decl. Ex. 42 (“Just trying to get up to speed . . . I was left out of the loop when this was agreed upon.”)

Many of the pedigrees sent by Rapids Tex and Mr. Unlimited were obviously fraudulent. For example, for hundreds of bottles of BIKTARVY®, the pedigrees claimed that Gilead initially sold the drugs not to an authorized distributor, but to an “independent pharmacy cooperative” in Wisconsin. Sunkara Decl. ¶ 45 & Ex. 6; *see also, e.g.*, Potter Decl. Ex. 43. In other pedigrees, Rapids Tex fraudulently claimed that Rapids acquired Gilead medication directly from AmerisourceBergen, a Gilead authorized distributor. Potter Decl. Ex. 44. As stated in the attached declaration of Bruce Gundy, AmerisourceBergen’s Director of Investigations, Amerisource Bergen never sold anything to Rapids Tex. Gundy Decl. ¶ 4; *see also* Sunkara Decl. ¶ 30.

**b. Safe Chain Creates New Fraudulent Pedigrees from Whole Cloth and Erases Rapid Tex’s Name Completely**

Safe Chain’s “pass through” scam had one shortcoming: the pedigrees it received from Mr. Unlimited still listed Rapids Tex as an upstream supplier. When the patient complaints continued to roll in and Gilead’s investigation intensified, Safe Chain began to create new

fraudulent pedigrees that simply erased Rapid Tex from the chain of sale completely. The following is an example from the files provided by The Medicine Shoppe:

SAFE CHAIN SOLUTIONS, LLC

**Drug Supply Chain Security Act Document** Doc# 00000021427

**(TI) Transaction Information**

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: 01144744 Document Type: Invoice Reference Date: 03/12/21											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Lot Number</th> <th style="text-align: left;">Quantity</th> <th style="text-align: left;">Unique Serial #</th> </tr> </thead> <tbody> <tr> <td>6400503A</td> <td>3</td> <td></td> </tr> <tr> <td>6400504A</td> <td>3</td> <td></td> </tr> <tr> <td>6400506A</td> <td>2</td> <td></td> </tr> </tbody> </table>	Lot Number	Quantity	Unique Serial #	6400503A	3		6400504A	3		6400506A	2			
Lot Number	Quantity	Unique Serial #												
6400503A	3													
6400504A	3													
6400506A	2													

**(TH) Transaction History**

Manufacturer's Name: GILEAD SCIENCES  
 Manufacturer's information: [REDACTED]

<b>SOLD TO:</b> Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Purchased & Ref : [REDACTED]	<b>SHIPPED TO:</b> Name: MR.UNLIMITED, LLC Address: ATTN:ACCOUNTS RECEIVABLE BRENHAM TX 77833 Date Received & Ref : [REDACTED]
<b>SOLD TO:</b> Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 03/08/21 PO#01212220	<b>SHIPPED TO:</b> Name: SAFE CHAIN SOLUTIONS - UT Address: 1812 W SUNSET BLVD ST. GEORGE UT 84770 Date Received & Ref : 03/11/21 RC#017605
<b>SOLD TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 03/12/21 01S40110001	<b>SHIPPED TO:</b> Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 03/12/21 01S40110001

Potter Decl. Ex. 45 (excerpted image; red rectangles added to show missing information). In this fraudulent pedigree – one of several provided by The Medicine Shoppe – Safe Chain claims that it bought from Mr. Unlimited, which bought directly from Gilead. That is, of course, untrue. Indeed, the pedigree is obviously fake. Safe Chain failed to list required information about that supposed sale from Gilead to Mr. Unlimited, such as Gilead's address, the date of that "sale," and the reference number.

**D. Safe Chain's Partnership with Indicted Health Care Fraudster Adam Brosius to Buy and Sell the Counterfeits**

Worldwide Pharma, sometimes under its d/b/a Pharma Sales, worked with Safe Chain to source, purchase, advertise, sell, and invoice the counterfeit HIV medication. Worldwide

Pharma's owner and principal, Defendant Brosius, was directly involved in this relationship. Since June 10, 2020 – well before Safe Chain's earliest known purchase or sale of counterfeit Gilead HIV medication – Brosius has been under indictment by a federal grand jury in the District of New Jersey. *See* Coleman Decl. Ex. 9.

As alleged in the indictment and corroborated by the allegations of various lawsuits filed against him, Brosius was the president and a board member of Main Avenue Pharmacy, Inc., in New Jersey ("Main Pharmacy"). *See* Coleman Decl. Exs. 8, 9. Main Pharmacy charged Brosius with the task of establishing a compliance program for the pharmacy. Instead, Brosius used his control of the pharmacy to commit massive fraud. Brosius caused Main Avenue to partner with a "marketing" company wholly owned by Brosius: Pharma Sales Group, Inc. ("Pharma Sales"), a predecessor to Worldwide Pharma. Under Brosius's direction, Main Avenue and Pharma Sales embarked on a vast prescription-drug fraud scheme resulted in the sale of \$35 million worth of fraudulently prescribed pharmaceuticals. *See* Coleman Decl. Exs. 8, 9. Brosius orchestrated the scheme himself, creating pre-preprinted prescription pads for doctors to "check off" fraudulent prescriptions; giving kickbacks to his marketing company based on the number of illegal insurance payments the pharmacy received; and even buying money orders to make it seem as though patients who did not want the fraudulently prescribed medications were paying their insurance co-pays. *See* Coleman Decl. Exs. 8, 9.

All of this was public knowledge and should have been known to Safe Chain when it partnered with Brosius. And yet Brosius's company Worldwide Pharma is prominently displayed on Safe Chain's website as one of its trusted partners. Coleman Decl. ¶ 24. The inescapable conclusion is that Brosius's indictment was not a deterrent – rather, to Safe Chain, it was an impressive-looking resume. Brosius's experience with fraudulent pharmaceutical

marketing and willingness to rip off innocent patients was what Safe Chain wanted in a partner in its scheme to sell dangerous counterfeit HIV medications.

**E. The FDA’s Formal Guidance Defines Virtually Every Aspect of Safe Chain’s Operation as Facilitating the Sale of Counterfeit Goods**

As mandated by the DSCSA, the FDA has released formal guidance for pharmaceutical distributors on how to identify suspect product and avoid purchasing illegitimate product. 21 U.S.C. § 360eee-1(a)(2). The FDA’s guidance “identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain,” and it reads like a checklist of the circumstances surrounding Safe Chain’s purchases of Gilead HIV medication:<sup>11</sup>

- “Purchasing from a source new to the trading partner.”
- “Purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable business practices that could increase the risk of suspect product entering the supply chain, such as:
  - “A trading partner that has been involved in business transactions where they sold or delivered illegitimate product
  - “A trading partner that has a history of problematic or potentially false transaction histories, such as those that contain misspelled words or incomplete information.
  - “A trading partner that is reluctant to provide a transaction history associated with the product being purchased, or does not do so in a timely manner.
  - “A trading partner that provides transaction information, a transaction statement, and/or transaction history [*i.e.*, a pedigree] that appears to be incomplete or questionable.”
- “Product that is generally in high demand in the U.S. market.”
- “Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).”
- “Product that has a high sales volume or price in the United States”
- “Product offered at a price ‘too good to be true.’”

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<sup>11</sup> Food and Drug Administration, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification – Guidance for Industry* (“FDA Guidance”), June 2021, <https://www.fda.gov/media/88790/download>, attached hereto as Potter Decl. Ex. 46.

- “Product that has been previously or is currently being counterfeited or diverted (e.g., HIV... drugs).”

FDA Guidance at 4-6. The FDA guidance also reminds distributors that under Section 582 of the DSCSA they are obligated to purchase only from “authorized” distributors – defined as distributors who are registered with the FDA and with appropriate state licensure – and should therefore “exercise due diligence” before purchasing from a supplier. *Id.* at 6.

There can be little doubt that Safe Chain, faced with this sea of red flags about its purchases of counterfeit Gilead HIV drugs from its unregistered and unlicensed suppliers, knew that it was not buying legitimate medication.

## **VI. WORLDWIDE PHARMA’S WILLFUL TRAFFICKING OF COUNTERFEIT HIV MEDICATION**

The evidence shows that Worldwide Pharma worked with Safe Chain on all aspects of its purchase, advertising, and sale of counterfeits. For example, Worldwide Pharma was listed as Gentek’s primary contact for its sales of counterfeits to Safe Chain. Potter Decl. Ex. 37.

Worldwide Pharma was involved in orchestrating and running the pass-through scam with Mr. Unlimited and Rapids Tex. Potter Decl. Ex. 38. Worldwide Pharma sent out the advertisements to pharmacies showing that Safe Chain was selling Gilead drugs at below WAC. Potter Decl. Ex. 34. And Worldwide Pharma acted as collection agent, sending out Safe Chain’s invoices to pharmacies for the illicit medication they were selling. Potter Decl. Ex. 47.

Based on the available evidence, it is feasible that Worldwide Pharma is directly in contact with the counterfeit manufacturers and has recruited the entire supply chain to get those counterfeits to patients. Worldwide Pharma’s role in the counterfeiting ring will be a focus of expedited discovery.

## **VII. BOULEVARD'S WILLFUL TRAFFICKING OF COUNTERFEIT HIV MEDICATION**

Boulevard's willful sale of counterfeit HIV medications is not subject to meaningful dispute. Both Gilead and an outside laboratory have confirmed that Boulevard sold counterfeits to Safe Chain. Sunkara Decl. ¶¶ 41, 56; Bienz Decl. ¶ 37. Boulevard provided fraudulent pedigrees for those counterfeits. Sunkara Decl. ¶¶ 40, 55. Gilead knows the pedigrees are fraudulent because they claim Boulevard purchased lots of Gilead products from an authorized distributor, but Gilead never sold those lots to that distributor. *Id.*

Boulevard of course knew that it had not purchased the counterfeits from the authorized distributor it named on its fraudulent pedigrees. And Boulevard's owner and principal, Shukurov, is an experienced health care fraudster. Coleman Decl. ¶¶ 17-18 & Ex. 7. It is simply impossible that Boulevard and Shukurov believed they were selling legitimate pharmaceuticals when they distributed dangerous counterfeit Gilead HIV medications into the U.S. supply chain.

## **ARGUMENT**

Gilead respectfully submits that the extraordinary facts of this case and the egregiousness of the Defendants' conduct make it clear that Gilead is entitled to the relief it seeks in this motion.

### **I. GILEAD IS ENTITLED TO AN *EX PARTE* SEIZURE ORDER**

Gilead seeks an *ex parte* seizure order pursuant to the Trademark Counterfeiting Act of 1984, 15 U.S.C. § 1116(d)(1). Gilead seeks the seizure to occur at three locations: the residence of Defendant Shukurov, the owner and principal of Boulevard, in Brooklyn; Safe Chain's combined headquarters and warehouse in Cambridge Maryland; and Safe Chain's distribution center in St. George, Utah.

Passed in response to “an ‘epidemic’ of commercial counterfeiting,” *see* S. Rep. No. 98-526, 98th Cong., 2d Sess. 5 (1984), reprinted in 1984 U.S.C.C.A.N. 3627, 3631 (citing *Montres Rolex, S.A. v. Snyder*, 718 F.2d 524, 528 (2d Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984)), the Counterfeiting Act permits a court to grant an *ex parte* order of seizure in “[c]ivil actions arising out of [the] use of counterfeit marks,” including seizure of counterfeit goods and “records documenting the manufacture, sale, or receipt” of the counterfeit goods. 15 U.S.C. § 1116(d)(1)(A). As Congress explained in the Senate Report accompanying this bill, “[t]he reason for this provision is that many counterfeiters, once given notice that their fraudulent operations have been discovered, will immediately dispose of the counterfeit goods and make it impossible for the trademark owner ever to bring them to justice.” 1984 U.S.C.C.A.N. at 3629.

**A. Gilead Satisfies All the Requirements for an *Ex Parte* Seizure Under the Counterfeiting Act**

The Counterfeiting Act enumerates several prerequisites for obtaining an *ex parte* seizure order. *See* 15 U.S.C. § 1116(d)(4)(B).<sup>12</sup> Gilead has satisfied all of them. Gilead therefore respectfully requests that the Court issue an *ex parte* seizure order. A proposed order is being filed simultaneously with this motion.

**1. An order other than an *ex parte* seizure order is not adequate to achieve the purposes of the Lanham Act (15 U.S.C. § 1116(d)(4)(B)(i))**

As set forth below, the Lanham Act’s goals are to protect manufacturer’s marks and goodwill, to allow manufacturers to control the quality of their products, and to protect the

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<sup>12</sup> The Counterfeiting Act separately requires plaintiffs to notify the local U.S. Attorney before seeking an *ex parte* seizure. 15 U.S.C. § 1116(d)(2). Gilead has done so. Potter Decl. ¶ 8 & Ex. 1. In its proposed seizure order, Gilead has also included a provision requiring a seizure bond pursuant to 15 U.S.C. § 1116(d)(4)(A).

American consumer from confusion. (*See* pp. 56-58, *infra.*) Here, Safe Chain and Boulevard are each engaged in the willful, wholesale distribution counterfeit, dangerous prescription HIV medications. The only feasible means of stopping Safe Chain and Boulevard, collecting the evidence of their counterfeiting, and tracing the distribution of these counterfeits is through an *ex parte* seizure.

As recognized by Congress in enacting the Counterfeiting Act, counterfeiters are more likely than not to dispose of or conceal the counterfeit goods when confronted with a trademark action. 130 Cong. Rec. H 12076, 12080 (“[M]any of those who traffic in counterfeits have become skilled at destroying or concealing counterfeit merchandise when a day in court is on the horizon.”). Here, both Safe Chain and Boulevard intentionally created fraudulent pedigrees, falsifying the very documents that the FDA requires as an anti-counterfeiting measure, in order to conceal their counterfeiting from Gilead and the government. (*See* pp. 13-14, 18-20, 42, *supra.*) Boulevard improved its fraudulent pedigrees over time, learning to claim on its forms that it purchased from an authorized Gilead distributor. And where Safe Chain appears to have initially been satisfied to rely on the fraudulent pedigrees provided by Boulevard and its other counterfeit suppliers, when Gilead’s investigation intensified, Safe Chain escalated to creating new fraudulent pedigrees itself.

Moreover, Gilead has already served federal discovery requests on both Boulevard and Safe Chain, in the form of third-party document subpoenas in the Florida Action. Boulevard was validly served but simply ignored the subpoena. Safe Chain refused to produce documents, and then resorted to an outrageous lie about its sourcing of Gilead products in a fraudulent attempt to get Gilead to withdraw that subpoena – and to release all claims Gilead had against Safe Chain.



The Counterfeiting Act's provision for *ex parte* seizures was enacted for precisely this type of scenario.

**2. Gilead has not publicized the requested seizure (15 U.S.C. § 1116(d)(4)(B)(ii))**

Gilead has not publicized the requested seizure. Potter Decl. ¶¶ 5-7. Gilead has moved for the papers in support of Gilead's application for *ex parte* relief to be kept under seal by the Clerk of this Court pending the effectuation of the seizure order.

**3. Gilead is likely to succeed in showing that the person against whom seizure would be ordered used a counterfeit mark in connection with the sale, offering for sale, or distribution of goods or services (15 U.S.C. § 1116(d)(4)(B)(iii))**

As demonstrated above, the indisputable evidence shows that Safe Chain and Boulevard have engaged in distributing, selling, and offering for sale a variety of counterfeit Gilead devices in counterfeit packaging that falsely bears Gilead's registered trademarks. (*See* pp. 7-12, 20-22, 42, *supra*.) Gilead is more than likely to succeed on its counterfeiting claims, and that is more than sufficient to satisfy this statutory criterion. (*See* pp. 55-58, *infra*.)

**4. An immediate and irreparable injury will occur if such seizure is not ordered (15 U.S.C. § 1116(d)(4)(B)(iv))**

As discussed below, Gilead (and others) are being irreparably harmed as Defendants' dangerous counterfeits medications are currently being distributed to, and used by, patients in the United States. (*See* pp. 59, *infra*). Seizing the counterfeit product and the documentation concerning its sale and distribution is a necessary first step to prevent Safe Chain and Boulevard from continuing to sell the counterfeits, to identify others who may be involved, and to warn customers who may have purchased counterfeit product. Until that happens, Gilead and the public will be irreparably injured.

**5. The matter to be seized will be located at the place identified in the application (15 U.S.C. § 1116(d)(4)(B)(v))**

The requested seizure will take place at three locations: Safe Chain's headquarters and warehouse in Cambridge, Maryland; Safe Chain's distribution center in St. George, Utah; and the current residence of Shukurov, the owner and principal of Boulevard, in Brooklyn.

Gilead has documentary evidence that counterfeits were delivered to both of Safe Chains' two warehouses, in Maryland and in Utah. Gilead's private investigators have recently visited both locations, and confirmed them both to be open, active businesses. Decl. of David M. Hopp, dated July 20, 2021 ("Hopp Decl.") ¶¶ 3-6; Decl. of Troy N. Tanner, dated July 20, 2021 ("Tanner Decl.") ¶¶ 3-7.

Boulevard has recently abandoned its offices at 9229 Queens Boulevard in Rego Park. A Gilead investigator visited the site and found that, although Boulevard's name still appears on a list of tenants near the entrance of the building, the unit that Boulevard previously occupied is now empty, with a "for sale" sign on the door. Decl. of Patrick McAllister, dated July 19, 2021 ("McAllister Decl.") ¶ 3-5.

Boulevard has not dissolved and has not cancelled its New York pharmacy licensure, but it also has not registered at a new address. Coleman Decl. ¶¶ 9-11. For several reasons, it seems very likely that Boulevard's principal, Shukurov, is laying low. First, Boulevard has now been identified as the upstream supplier for multiple patient complaints of counterfeit HIV medication. Second, Safe Chain has recently stated that it stopped buying from Boulevard, so it has lost a major source of income. And third, Shukurov's co-conspirator was recently indicted for using Shukurov's other pharmacy as part of a massive prescription drug fraud scheme.

Using skip tracing techniques, Gilead's private investigators identified Shukurov's current residence: 3110 Brighton Seventh Street, #2B, Brooklyn. McAllister Decl. ¶ 6. An

investigator went to that address under the pretense of making a delivery and confirmed Ishbay's presence there: the investigator met a man who matched the photo on Shukurov's Facebook profile at the door of the residence, and the man confirmed his name was Ishbay and accepted the delivery. *Id.* ¶¶ 7-10.

Given that Shukurov has abandoned the company's offices – the offices that gave it its name, Boulevard 9229 – and appears to be avoiding attention, the evidence strongly suggests that Shukurov will at least have electronic records concerning his and his company's counterfeiting at his residence.

**6. The harm to the applicant of denying the application outweighs the harm to the legitimate interests of the person against whom seizure would be ordered (15 U.S.C. § 1116(d)(4)(B)(vi))**

Safe Chain and Boulevard have no legitimate interest in selling counterfeit Gilead medication, and no legitimate interest in selling prescription medication that must be quarantined pursuant to the DSCSA because it is the subject of a fraudulent pedigree. *Koon Chun Hing Kee Soy & Sauce Factory, Ltd. v. Kun Fung USA Trading*, No. 07-CV-2568 (CPS), 2007 WL 9723382, at \*5 (E.D.N.Y. July 19, 2007) (“[T]o the extent that items seized are counterfeit, defendants have no legitimate interest in the physical goods to be seized.”). The Defendants therefore cannot suffer any harm from the seizure of such goods. Shukurov likewise has no legitimate interest in storing counterfeits or documents concerning the counterfeits at his personal residence. Gilead, on the other hand, has a very strong interest in protecting the public's health and safety, as well as its own trademarks and goodwill, from the counterfeits that Defendants are selling. (*See* pp. 6-12, *supra*.)

**7. Defendants would destroy, move, hide, or otherwise make such matter inaccessible to the court, if the applicant were to proceed on notice to such person (15 U.S.C. § 1116(d)(4)(B)(vii))**

As noted above, Congress determined in passing the Counterfeiting Act that counterfeiters “have become skilled at destroying or concealing counterfeit merchandise when a

day in court is on the horizon.” 130 Cong. Rec. H12076, at 12080. Here, the counterfeits are bottles of prescription HIV medication: small, lightweight, easily movable, and extremely high-value products. Tens of millions of dollars’ worth of these products can fit in the trunk of a car and be driven away on a moment’s notice. And the evidence shows that the Defendants maintain records of the sale of these counterfeits electronically, making them easy to delete *en masse*.

Boulevard is a classic fly-by-night counterfeiter. It was recently established, only briefly operated out of a small office before disappearing, had no licensure whatsoever to distribute pharmaceutical medication, and appears to have been a one-man shop. Shortly after patient reports of Boulevard-trafficked counterfeits came to light, Boulevard moved out of its office. Coleman Decl. ¶¶ 9-15; McAllister Decl. ¶¶ 3-5. And when Gilead served Boulevard with a federal subpoena, it simply ignored it. The risk of Boulevard destroying or hiding counterfeit product and documents concerning its counterfeiting is very high.

Safe Chain uses its established business presence to dupe pharmacies into purchasing counterfeits that Safe Chain illegally and knowingly sourced from unlicensed and unregistered fly-by-night wholesalers, like Boulevard. Safe Chain directly falsified its pedigrees to pharmacies, and orchestrated a “pass-through” scam to whitewash its counterfeits.

When Gilead first approached Safe Chain about its counterfeiting, treating Safe Chain as though it to were a victim, Safe Chain repaid Gilead by slow-walking its responses so that it could keep buying thousands of more bottles from its counterfeit suppliers; concealing earlier reports of counterfeit medication and later falsely claiming to have reported them; and secretly encouraging pharmacies that received the counterfeits to return the product directly to Safe Chain, without notifying Gilead. In at least one instance – and there are likely more – Safe Chain deliberately altered a pedigree before sending it to Gilead by adding in a false purported

sale to an authorized distributor. (*See* pp. 17-19, *supra*.) And in a brazen attempt to trick Gilead into withdrawing a subpoena and releasing its claims, Safe Chain told an outrageous lie, claiming to have verified that it was now buying from a supplier who was purchasing directly from a Gilead authorized distributor, when in reality it was continuing to buy from yet another shady, unlicensed, fly-by-night distributor who used fraudulent pedigrees to sell black-market product. (*See* pp. 24-28, *supra*.) Safe Chain simply cannot be trusted.

Notably, Safe Chain was represented by outside counsel throughout its interactions with Gilead: in responding to Gilead's notices of patient complaints about counterfeits, in responding to Gilead's requests for more information, and in response to Gilead's subpoena. Gilead has no reason to believe that Safe Chain's outside counsel was aware that its client was lying about falsifying pedigrees, or lying when it said it was finally buying from a legitimate seller whose purchases from an authorized distributor had been personally verified by Safe Chain. Rather, the point is that Safe Chain has a proven record and established practice of lying to its outside counsel, and using outside counsel to convey falsehoods that allow Safe Chain to continue covering up its counterfeiting. There is no reason to believe that if Safe Chain were sued through normal service of process, it would suddenly come clean and begin telling the truth to its lawyers.

Finally, by knowingly trafficking counterfeit HIV medications Safe Chain and Boulevard engaged in criminal counterfeiting. *See* 18 U.S.C. § 2320. They also committed the crime of selling misbranded drugs, which is one of very few federal strict-liability crimes, and which carries substantial jail time when done knowingly. 21 U.S.C. § 331. As detailed above, they also committed a host of violations of the DSCSA. And, of course, both the corporate and individual Defendants are all subject to extensive civil liability for their actions. The incentives

for Defendants to cover up their criminal behavior are clear, as is their history of fraudulently concealing their counterfeiting and flouting federal discovery. Boulevard and Safe Chain are precisely the type of defendants that Congress had in mind when it authorized *ex parte* seizure orders in the Counterfeiting Act.

**B. The Proposed Seizure Order Provides for Additional Protections to Protect Defendants' Attorney-Client Privilege**

Any seizure carries some risk of capturing attorney-client communications, which the parties typically address after the seizure is executed. But here, because Safe Chain utilized outside counsel in its communications with Gilead and its response to the subpoena, Gilead believes additional steps should be taken during the seizure to protect any attorney-client privileged documents. Although there is no indication that Boulevard or Shukorov is currently represented, in an abundance of caution Gilead suggests that these extra protections should be offered to those Defendants as well.

As is commonly done during *ex parte* seizures, the proposed seizure order provides that an outside and independent data vendor will copy and maintain the electronically stored information located on the premises: *i.e.*, the data and documents from computers, phones, servers, and other electronic devices. In order to protect Defendants' privilege, the proposed seizure order goes further, and provides that Gilead's counsel shall not be provided access to the seized electronic documents. Instead, all documents will be reviewed in the first instance by the independent third-party data vendor who will send the relevant documents to Defendants' counsel to give them an opportunity to object before the documents are released to Gilead.

Specifically, Gilead's counsel would work with the data vendor, UnitedLex, to decide what search terms to run and what categories of documents to look for. UnitedLex would then run the searches and conduct the review, using in-house employees experienced in such reviews.

The documents selected by UnitedLex would first be provided to Safe Chain's and Boulevard's respective counsel, who would have 24 hours to assert privilege over any documents before they are provided to Gilead. Any documents over which privilege is claimed would be set aside and entered by the respective Defendants on a privilege log; the remaining documents would be produced to Gilead. The order provides, and Gilead will stipulate, that the collection of documents at the seizure and/or their review by UnitedLex shall not on its own constitute a waiver of any privilege or immunity.

UnitedLex is a global technology and legal services company with over three thousand employees. Decl. of Ryan Frye, dated July 21, 2021 ("Frye Decl.") ¶ 2. It is more than capable of collecting and maintaining the data and conducting this type of review. *Id.* ¶¶ 8-9. In fact, UnitedLex has recently performed this precisely service in connection with an *ex parte* seizure ordered by then-Chief Judge Amon of this Court,<sup>13</sup> as well as a separate *ex parte* seizure ordered by Judge Dow of the U.S. District Court for the Northern District of Illinois.<sup>14</sup> In each of those cases, there were similar concerns about privilege because of ongoing litigation between the parties or discussions between the parties about counterfeiting in connection with the issuance of a subpoena. A copy of the most recent of these seizure orders, from Judge Dow in the Northern District of Illinois, is attached to the Potter Declaration as Exhibit 2.

This privilege-review procedure will allow for the relatively rapid production of documents while ensuring Gilead never sees a Safe Chain or Boulevard document that has not

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<sup>13</sup> *Abbott Labs. et al. v. H&H Wholesale Servs., Inc. et al.*, No. 17-cv-3095 (CBA) (LB) (E.D.N.Y.).

<sup>14</sup> *Johnson & Johnson et al. v. Advanced Inventory Management, Inc. d/b/a eSutures.com et al.*, No. 20-cv-341 (N.D. Ill.).

been first reviewed by their respective counsel. The biggest downside is that this procedure has the potential to delay Gilead's access to the documents and information it needs most urgently: *e.g.*, the identities of Defendants' suppliers of counterfeit Gilead medication and the identities of the customers who purchased the counterfeits. That information will allow Gilead to immediately begin tracking down the already-sold counterfeits and any additional counterfeiters. The proposed seizure order therefore requires Defendants to produce that information themselves, and to do so as soon as practicable after the seizure is commenced. Knowing that Gilead has already seized their documents will incentivize Defendants to be truthful in self-disclosing that information.

**C. The Seizure Should Include Copying Mobile Devices**

Because Safe Chain refused to provide its communications with Boulevard, Gilead does not know in which medium their communications occurred. But in the undersigned counsel's experience, it is extremely common for counterfeiters to use messaging apps on their smart phones, such as WhatsApp, to conduct business. These messaging apps are tied to specific cell phone numbers and have end-to-end encryption, meaning the communications cannot be downloaded from a server and exist only on the users' phones. Because WhatsApp and similar communications can only be downloaded directly from the sender or recipient's mobile phone, it is essential that the seizure order provide that Gilead may copy any mobile devices found on the premises, including those being carried by persons present at the time of the seizure. WhatsApp messages and similar communications can quickly and easily be permanently deleted, either remotely or on the phone itself, making it crucial that phones be quickly copied at the time of the seizure, before word spreads and the Defendants have the opportunity to destroy evidence. The process of copying the data on mobile phones can be done quickly on the spot, and Gilead's data vendor will make the copy without otherwise affecting the phone or its data.



#### **D. The Seizure Order Should Include All Gilead Products**

The proposed seizure order provides for the seizure of all Gilead products located on the premises. Gilead has tested and confirmed counterfeits of BIKTARVY® and DESCOVY®. But the counterfeiters also traded large volumes of almost the entirety of Gilead's prescription drug portfolio, including ATRIPLA®, GENVOYA®, COMPLERA®, EMTRIVA®, EPCLUSA®, ODEFSEY®, SOVALDI®, STRIBILD®, TRUVADA®, VIREAD®, VOSEVI®. *See, e.g.,* Potter Decl. Exs. 19, 47. For the reasons set forth above, the counterfeits that have come to Gilead's attention so far are almost certainly just the tip of the iceberg. And the process of manufacturing these counterfeits, which involves re-sealing or re-labeling an authentic bottle, could easily be applied to any bottle of Gilead medication, not just BIKTARVY® and DESCOVY®. The available evidence strongly supports the conclusion that there are likely other Gilead drugs being counterfeited.

Moreover, the evidence shows that all of the Gilead medications purchased and sold by Boulevard and Safe Chain were sourced from unlicensed and unregistered distributors and were accompanied by fraudulent pedigrees, meaning they are unlawful to sell and must be quarantined pursuant to the DSCSA. 21 U.S.C. § 360eee-1(c)(4)(a)(i); *see pp. 31-38, supra*. Moreover, even if not counterfeit, Gilead products sold with altered or falsified pedigrees infringe Gilead's trademarks. *See* 15 U.S.C. § 1125(a); *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 242-246 (2d Cir. 2009). Even if any of those fraudulently trafficked drugs are not counterfeit, there can be no harm to Defendants by the seizure of illegally traded, infringing bottles of medication that cannot lawfully be re-sold. And if, contrary to the available evidence, Defendants were to also have authentic, legitimately purchased, salable Gilead product in their possession, they should have no difficulty proving that to Gilead, in which case the legitimate drugs can be returned. Given the evidence of Defendants' widespread, willful counterfeiting, that potential

inconvenience is more than reasonable, and is strongly outweighed by Gilead's and the public's interest in shutting down Defendants' counterfeiting of Gilead medication.

**E. This Court Has Authority to Order Seizures Anywhere in the United States**

Gilead seeks a seizure to occur within this District (Shukurov's residence in Brooklyn) and in other states (Safe Chain's facilities in Maryland and Utah). The fact that Safe Chain's office and warehouse are in different states does not affect this Court's ability to issue the requested *ex parte* seizure order. This Court has personal jurisdiction over Safe Chain because, among other reasons, it sold counterfeit Gilead HIV medication to pharmacies in New York City. Sunkara Decl. Exs. 2, 3. A party who is subject to this Court's jurisdiction is subject to injunctive relief anywhere in the United States it happens to be. *See, e.g., Tiffany (NJ) LLC v. Forbse*, No. 11 Civ. 4976 (NRB), 2012 U.S. Dist. LEXIS 72148, at \*31-38 (S.D.N.Y. May 23, 2012) ("Given that the Court has personal jurisdiction over both defendants and the Banks, the Court's authority to restrain defendants' assets that are controlled by the Banks extends to wherever those assets may be located." (internal citations omitted)); *United States v. First Nat'l City Bank*, 379 U.S. 378, 384, (1965) ("Once personal jurisdiction of a party is obtained, [a district court] has authority to order it to 'freeze' property under its control, whether the property be within or without the United States.").<sup>15</sup> There is no geographical limitation on a District Court's ability to order an *ex parte* Seizure under the Counterfeiting Act, *see* 15 U.S.C.

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<sup>15</sup> Although non-party subpoenas under Federal Rule of Civil Procedures are to be enforced in the district "where compliance is required," this requirement is based on the language of Rule 45 and is not jurisdictional. Fed. R. Civ. P. 45(d)(2)(B)(i) (providing for motions to compel to be filed in the district "where compliance is required"); *see AngioScore, Inc. v. TriReme Med., Inc.*, No. 12-cv-03393-YGR (JSC), 2014 U.S. Dist. LEXIS 165227, at \*4 (N.D. Cal. Nov. 25, 2014) (explaining that requirements for venue in filing subpoena-related motions are based on the text of Rule 45 and that jurisdiction would exist in the issuing court but for the language of the Rule).

§ 1116(d), and this Court and others regularly order *ex parte* seizures to occur throughout the United States, not just in their home jurisdictions. *See, e.g., Abbott Labs. v. Adelphia Supply USA*, No. 15-cv-5826, 2019 U.S. Dist. LEXIS 75364 (E.D.N.Y. May 2, 2019) (describing seizure order issued in E.D.N.Y. and executed against defendants in Michigan); *Araca Merch. L.P. v. Doe*, Civ. Action No. H-16-1194, 2016 U.S. Dist. LEXIS 64934 (E. D. Tex. May 5, 2016) (issuing seizure order to be executed by “the United States Marshal, for this District or any district in which Plaintiff enforces this order” for tour traveling across United States); *Cartier Int’l B.V. v. Ben-Menachem*, No. 06-cv-3917(RWS), 2007 U.S. Dist. LEXIS 95366, 2008 WL 64005 (S.D.N.Y. Dec. 19, 2007) (describing seizure order issued from S.D.N.Y. against defendants in E.D.N.Y.); *Bear U.S.A., Inc. v. Kim*, 71 F. Supp. 2d 237, 244-45 (S.D.N.Y. 1999) (describing the issuance of *ex parte* seizure order in S.D.N.Y. directed at counterfeit products produced by a Chinese company and imported by its United States subsidiary, where the counterfeit parkas were located in a New Jersey warehouse); *Gore v. Various John Does*, No. 98-cv-7576(DLC), 1998 U.S. Dist. LEXIS 17596, 1998 WL 778374 (S.D.N.Y. Nov. 6, 1998) (issuing seizure order to be executed by “the United States Marshal(s) for this district and for any district in which plaintiffs seek to enforce this Order” for tour traveling across United States).

## **II. GILEAD IS ENTITLED TO A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION**

“Federal courts have long recognized the need for immediate injunctive relief in trademark infringement cases due to the amorphous nature of the damage to the trademark and the resulting difficulty in proving monetary damages.” *Multi-Local Media Corp. v. 800 Yellow Book, Inc.*, 813 F. Supp. 199, 202 (E.D.N.Y. 1993). Here, Gilead seeks a temporary restraining order to stop Defendants’ trafficking of counterfeit Gilead medication and ensure that evidence, including the counterfeit product itself, is preserved. To obtain such relief, Plaintiffs must

demonstrate “that [they are] likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Gilead easily meets all of those elements and therefore is entitled to immediate injunctive relief.

#### **A. Gilead Has a Strong Likelihood of Success on the Merits**

Among other claims, Gilead has alleged various causes of action against Defendants for violating Gilead’s trademark rights under the Lanham Act and state law. Gilead can prevail on its trademark claims by showing “(1) that it owns a valid, protectable trademark; (2) that the defendants used the registrant’s trademark in commerce and without consent; and (3) that there was a likelihood of consumer confusion.” *Proctor & Gamble Co. v. Quality King Distribs., Inc.* 123 F. Supp. 2d 108, 113 (E.D.N.Y. 2000); *see also Tanning Research Labs., Inc. v. Worldwide Imp. & Exp. Corp.*, 803 F. Supp. 606, 608-09 (E.D.N.Y. 1992).

None of these elements is remotely in question here. Gilead owns multiple distinct, valid registered trademarks for the products at issue. Stroud Decl. ¶ 4. Defendants are “using” those marks in interstate commerce by advertising, buying, and selling counterfeit Gilead drugs. There also can be no dispute that Defendants are not authorized to use Gilead’s marks to sell counterfeits. *Id.* ¶¶ 11-13. The fact that the counterfeits were manufactured in part by using once-authentic Gilead packaging does not, of course, alter the fact that these are counterfeit products – *i.e.*, products in bottles bearing Gilead’s registered marks without permission, when in fact the bottles contain an entirely different product than those indicated by the marks. *E.g.*, *Westinghouse Elec. Corp. v. Gen. Circuit Breaker & Elec. Supply, Inc.*, 106 F.3d 894, 900 (9th Cir.1997) (“When an original mark is attached to a product in such a way as to deceive the public, the product itself becomes a ‘counterfeit’ just as it would if an imitation of the mark were

attached.”); *U.S. v. Petrosian*, 126 F.3d 1232, 1233-34 (9th Cir. 1997); *Cartier v. Aaron Faber Inc.*, 512 F. Supp. 2d 165, (S.D.N.Y. 2007) (holding that watches that retained the manufacturer’s original marks, but were significantly altered by the defendant, “constitute ‘counterfeit’ merchandise for purposes of the Lanham Act.”).<sup>16</sup>

Because Defendants sold counterfeits that used once-authentic Gilead bottles and were intended to look exactly like new, sealed, genuine Gilead product, likelihood of consumer confusion is established as a matter of law. *See El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 396 (2d Cir. 1986) (holding “it is plain” that the sale of products that are “not genuine” violates the Lanham Act); *Omega Importing Corp. v. Petri-Kine Camera Co.*, 451 F.2d 1190, 1194 (2d Cir. 1971) (Friendly, C.J.) (“The probabilities of confusion from the sale of another [product] bearing the identical name are too obvious to require detailed proof.”); *Koon Chun Hing Kee Soy & Sauce Factory*, 2007 U.S. Dist. LEXIS 1404, at \*32-33; *Lorillard Tobacco Co. v. Jamelis Grocery, Inc.*, 378 F. Supp. 2d 448, 455 (S.D.N.Y. 2005); *Philip Morris USA, Inc. v. Felizardo*, No. 03-CV-5891(HB), 2004 U.S. Dist. LEXIS 11154, at \*18 (S.D.N.Y.

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<sup>16</sup> Defendants Safe Chain, Worldwide Pharma, and Boulevard are liable as corporate entities that bought and sold, and facilitated the purchase and sale of, the counterfeit products. The individual Defendants are jointly and severally liable with the corporation as agents and officers who participated in, directed, controlled, ratified, and/or supervised the corporation’s infringement. *E.g.*, *KatiRoll Co. v. Kati Junction, Inc.*, 2014 U.S. Dist. LEXIS 96826, at \*11-12 (S.D.N.Y. July 16, 2014) (“It is well-established . . . under the Lanham Act, a corporate officer may be held personally liable for trademark infringement . . . if the officer is a moving, active, conscious force behind the defendant corporation’s infringement.”); *Matsunoki Grp., Inc. v. Timberwork Or., Inc.*, 2009 U.S. Dist. LEXIS 37573, at \*9 (N.D. Cal. Apr. 16, 2009) (“A plaintiff may show that a corporate employee is [a] moving, active, conscious force behind the infringing activity by demonstrating that [he or she] direct[ed], control[led], ratifie[d], or participate[d] in the infringing activity.”). Moreover, any Defendant who “ha[d] the ability to supervise [the company’s] infringing activity and . . . had a financial interest in that activity” but failed to stop the infringement is individually liable. *Johnson & Johnson Consumer Cos. v. Aini*, 540 F. Supp. 2d 374, 393-94 (E.D.N.Y. 2008).

June 17, 2004) (“[C]ounterfeit marks are inherently confusing.”); *Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 286 F. Supp. 2d 284, 287 (S.D.N.Y. 2003) (“[C]ounterfeits, by their very nature, cause confusion.”); *Procter & Gamble Co.*, 123 F. Supp. 2d at 115 (“It would be difficult to imagine a clearer case of consumer confusion than the instant case in which defendants, acting in direct competition with the plaintiff, sold counterfeit products on which plaintiff’s registered marks appear in their entirety.” (citation omitted)).<sup>17</sup>

Notably, while there is extremely strong evidence that each of the Defendants knowingly and intentionally engaged in the sale of counterfeits, trademark infringement is a strict liability offense. *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 25 (2d Cir. 2004) (“[I]t is well established that wrongful intent is not a prerequisite to an action for trademark infringement . . . and that good faith is no defense.” (citations and internal quotations omitted)); *Hard Rock Café Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1152 n.6 (7th Cir. 1992) (“Sellers bear strict liability for violations of the Lanham Act.”); *Taubman Co. v. Webfeats*, 319 F.3d 770, 775 (6th Cir. 2003); *Philip Morris USA Inc. v. Shalabi*, 352 F. Supp. 2d 1067, 1073-74 (C.D. Cal. 2004). Therefore, defendants are liable under the Lanham Act regardless of whether they were aware of the counterfeit nature of the products they sold. *Id.*; *Philip Morris USA Inc. v. Liu*, 489 F. Supp. 2d 1119, 1122 (C.D. Cal. 2007). Gilead’s Lanham Act claims are not merely likely, but virtually certain to succeed.

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<sup>17</sup> Because counterfeit marks are inherently confusing, there is no need to analyze the so-called *Polaroid* factors to determine the likelihood of confusion between the genuine and the counterfeit goods. *Jamelis Grocery*, 378 F. Supp. 2d at 455 (citing *Polaroid Corp. v. Polarad Elecs. Corp.*, 287 F.2d 492, 495-96 (2d Cir. 1961)). Counterfeits create consumer confusion as a matter of law. *Id.*

**B. Gilead Is Suffering Irreparable Harm as a Result of Defendants’ Activities**

Because Gilead has demonstrated a likelihood of success on the merits on its Lanham Act claims, it is entitled to a rebuttable presumption of irreparable harm as a matter of law pursuant to the Trademark Modernization Act of 2020. 15 U.S.C. § 1116(a).

Even without that presumption, where, as here, a Lanham Act plaintiff has succeeded in showing a likelihood of confusion, irreparable injury “almost inevitably follows.” *Omega Importing Corp.*, 451 F.2d at 1195. The reason is simple: “because the losses of reputation and goodwill and subsequent loss of customers that Plaintiff will suffer are not precisely quantifiable[,] remedies at law cannot adequately compensate Plaintiff for its injuries.” *Pretty Girl, Inc. v. Pretty Girl Fashions, Inc.*, 778 F. Supp. 2d 261, 270 (E.D.N.Y. 2011); *see also Church of Scientology Int’l v. Elmira Mission*, 794 F.2d 38, 44 (2d Cir. 1986) (“[A]llowing defendants the opportunity to reduce the marks’ reputational value and goodwill by its continued unauthorized use constitutes the irreparable harm that is requisite to the issuance of the preliminary injunction.”); *New York City Triathlon, LLC v. NYC Triathlon Club, Inc.*, 704 F. Supp. 2d 305, 325 (S.D.N.Y. 2010) (“It is well-settled that a trademark owner’s loss of goodwill and ability to control its reputation constitutes irreparable harm sufficient to satisfy the preliminary injunction standard.”).

There is no question that Defendants sale of dangerous counterfeits of Gilead’s life-saving HIV medications is causing great harm to Gilead’s goodwill, and that its continued sale will irreparably harm Gilead. Stroud Decl. ¶¶ 12-13. Immediate injunctive relief is, therefore, necessary to prevent further damage to Gilead’s reputation and goodwill – and, of course, to patient health and safety, none of which can be undone.

### **C. The Balance of Equities Tips Decisively in Gilead's Favor**

Here, the equities emphatically support the issuance of a temporary restraining order. First and foremost, the counterfeit products pose a serious threat to patient health and safety. (*See pp. 10-12, supra.*) Quite apart from the harm to Gilead's goodwill, this threat to public health justifies immediate injunctive relief. *See, e.g., Burger King Corp. v. Stephens*, No. 89-CV-7691, 1989 U.S. Dist. LEXIS 14527 at \*33 (E.D. Pa. Dec. 6, 1989).

Because the law recognizes no excuse for selling counterfeit goods, the harm to Gilead should the requested injunction be denied far outweighs the harm to Defendants if their conduct is preliminarily enjoined. Each and every sale of counterfeit Gilead medication infringes Gilead's trademarks and causes harm to Plaintiffs' reputation. *See Microsoft Corp. v. ATEK 3000 Computer, Inc.*, No. 06-CV-6403 (SLT)(SMG), 2008 U.S. Dist. LEXIS 56689, at \*17 (E.D.N.Y. Jul. 23, 2008). The Defendants have no right to sell counterfeit Gilead medication, and no right to buy or sell medication with fraudulent pedigrees. (*See pp. 12-14, supra.*) Defendants thus cannot validly claim hardship based on the proposed injunctive relief.

### **D. An Injunction Is in the Public Interest**

The public interest in an injunction is self-evident in this case. It is in the public interest to prevent the sale of potent antipsychotics and other medication being sold in bottles masquerading as authentic Gilead HIV medication. It is also in the public interest to prevent confusion and protect informed choice when patients' health is at stake. *Cytosport, Inc. v. Vital Pharms., Inc.*, 617 F. Supp. 2d 1051, 1081 ("When a trademark is said to have been infringed, what is actually infringed is the right of the public to be free of confusion and the synonymous right of the trademark owner to control his products' reputation.") (E.D. Cal. 2009) (internal citation omitted); *Int'l Kennel Club of Chicago, Inc. v. Mighty Star, Inc.*, 846 F.2d 1079, 1092 n.8 (7th Cir. 1988) ("[T]he relevant consideration in determining whether the public interest will



be disserved by the grant of an injunction is the consumer's interest in not being deceived about the products they purchased.'" (alteration omitted)).

**E. Gilead Has Moved Expeditiously to Investigate the Counterfeiting and Bring This Action**

Gilead's investigation leading to this lawsuit has been diligent and expeditious. As set forth above, rather than immediately run to court when it became aware of the reports of Defendants' counterfeiting, Gilead followed its internal quality control procedures and conducted a thorough investigation, including collecting and testing numerous counterfeit samples both internally and in conjunction with an outside lab; confirming that it was impossible for the foreign tablets to have been inserted in the bottles at the original manufacturing or bottling facilities; tracing numerous fraudulent pedigrees, including confirming with all listed authorized distributors that transaction histories were falsified; and interviewing pharmacies and patients who received the counterfeits.

Moreover, in the Florida Action Gilead discovered a major source of illegally diverted Gilead medication, as well as evidence of Gilead medication being that was removed from authentic Gilead bottles. Gilead therefore in the Florida Action served third-party subpoenas on Boulevard, Mr. Unlimited, and Safe Chain in May. And while Boulevard ignored the subpoena and Safe Chain refused to produce documents unless Gilead withdrew the subpoena and signed a release of claims, Mr. Unlimited provided the requested discovery on May 27, 2021. Mr. Unlimited's production is how, among other things, Gilead learned of Safe Chain and Worldwide Pharma's "pass-through" scam, and later allowed Gilead to confirm that Safe Chain was creating fraudulent pedigrees when it sold to pharmacies.

Gilead also engaged in extensive correspondence with Safe Chain. Gilead originally treated Safe Chain as a legitimate distributor who had mistakenly purchased counterfeits.

Described above is Safe Chain's history of slow-walking its responses to Gilead's requests for basic information, concealing known instances of counterfeiting and then falsely claiming to have reported it, and refusing to fully cooperate in Gilead's investigation. But Safe Chain did in many instances eventually provide pedigrees and other information concerning its purchases. Safe Chain did also notify Gilead of new patient complaints about counterfeits (albeit many days after the fact, and well after Safe Chain had already secured a refund from its suppliers), and in some instances provided the counterfeit bottles to Gilead. Safe Chain at various points also stated that it was quarantining Gilead products in its inventory and, as the number of reports about its counterfeit suppliers continued to rise, claimed it had stopped or at least temporarily frozen its purchases of Gilead products from those suppliers. Thus, while Safe Chain's participation in Gilead's investigation was highly delayed, incomplete, and frustrating, Gilead also had reason to believe that it was making progress in shutting down Safe Chain's sales of counterfeits and tracing the counterfeit distribution chain. A full collection of Gilead's correspondence with Safe Chain is attached as Exhibit 7 to the Potter Declaration.

Gilead also cooperated with, and continues to cooperate with, the FDA Office of Criminal Investigation's ongoing criminal investigation. The FDA OCI originally requested that Gilead hold off taking legal action against certain of the counterfeiters.

The time Gilead spent prior to filing this action is fully justified by Gilead's "good faith efforts to investigate the alleged infringement," *Life After Hate v. Free Radicals Project, Inc.*, 410 F. Supp. 3d 891, 910 (N.D. Ill. 2019) (quoting *Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995)) – efforts that were substantially hampered by Defendants' fraudulent pedigrees, concealment of information, and severe delays in responding to Gilead's requests. The law correctly encourages markholders to investigate and engage in self-help rather

than immediately file suit when they learn of an infringing act. *Id*; see also, e.g., *Abbott Labs. v. Adelpia Supply USA*, No. 15-CV-5826, 2015 WL 10906060, at \*12 (E.D.N.Y. Nov. 6, 2015), *aff'd* 670 F. App'x 6 (2d Cir. 2016).

Separately, Gilead's decision to comply with the FDA OCI's request makes this motion timely. Courts have recognized that cooperation with federal criminal investigations justifies a delay in bringing related civil litigations. See, e.g. *Abbott Labs.*, 2015 WL 10906060, at \*12 (issuing preliminary injunction despite delay in bringing suit, and concluding "at no time was Abbott sleeping on its rights and delaying without reason" where, among other things, Abbott "coordinated with FDA OCI" and "FDA OCI explicitly asked Abbott to delay pursuing actions against" a defendant).

Gilead brings this action now on an urgent and *ex parte* basis for two reasons. First, Gilead was able to convince one of Safe Chains' customers who received the counterfeits, the Medicine Shoppe to voluntarily produce documents. Gilead received those documents on or about June 1, 2021. The Medicine Shoppe's documents showed Safe Chain's history of lying to pharmacies about Gilead, and asking them to return counterfeit product to Safe Chain without notifying Gilead. The Medicine Shoppe also provided Gilead its first direct evidence that Safe Chain was itself manufacturing fraudulent pedigrees to conceal its sourcing of product from Rapids Tex. And, most critically, The Medicine Shoppe provided the evidence that Safe Chain's claim to have a new supplier purchasing directly from a Gilead authorized distributor to be completely false and a knowing lie, and that Safe Chain was in fact simply continuing to buy from yet another unregistered, fly-by-night supplier selling purported Gilead medication accompanied by fraudulent pedigrees.

Second, while Gilead's cooperation with FDA OCI continued, on June 30, 2021 Gilead received a call from a separate branch of the FDA (at its request) concerning the mounting number of reports of Gilead counterfeits. On that call, the FDA encouraged Gilead to take appropriate corrective action to protect patients from counterfeit products in the supply chain.

### **III. GILEAD IS ENTITLED TO EXPEDITED DISCOVERY**

Gilead also respectfully seeks a limited expedited discovery order so that it may quickly investigate the distribution of counterfeit Gilead products in an effort to permanently banish them from the market. The expedited discovery order proposed here is functionally identical to orders previously granted by judges in this District in anti-counterfeiting actions involving *ex parte* seizures, examples of which are attached as Exhibit 5 to the Potter Declaration.

Federal courts have broad discretion to expedite the normal pace of discovery in cases seeking temporary or preliminary injunctive relief. 28 U.S.C. § 1657 directs that “the court shall expedite the consideration of . . . any action for temporary or preliminary injunctive relief.” Rule 26(d) of the Federal Rules of Civil Procedure allows for expedited discovery and an Advisory Committee comment to that rule notes that expedited discovery “will be appropriate in some cases, such as those involving requests for a preliminary injunction.” Fed. R. Civ. P. 26(d) and Advisory Comm. Note. Rule 30(a)(2)(A)(iii) provides that the Court may grant leave to take depositions “before the time specified” in the discovery rules. Similarly, Rule 34(b)(2)(A) provides that “[a] shorter or longer time may be . . . ordered by the court” for the production of documents than the rules would otherwise allow. Congress recognized that there is a special need for expedited discovery in counterfeiting cases, specifying in the Trademark Counterfeiting Act that a court may modify the time limits for discovery “to prevent the frustration of the purposes of [a seizure order] hearing.” 15 U.S.C. § 1116(d)(10)(B).

The standard for obtaining expedited discovery closely resembles the standard for obtaining preliminary injunctive relief. Four factors must be considered: “(1) irreparable injury, (2) some probability of success on the merits, (3) some connection between the expedited discovery and the avoidance of the irreparable injury, and (4) some evidence that the injury [that] will result without expedited discovery looms greater than the injury that the defendant will suffer if the expedited relief is granted.” *Gidatex, S.R.L. v. Campaniello Imports, Ltd.*, 13 F. Supp. 2d 417, 420 (S.D.N.Y. 1998); *Twentieth Century Fox Film Corp. v. Mow Trading Corp.*, 749 F. Supp. 473, 475 (S.D.N.Y. 1990).

Like injunctive relief, expedited discovery “is routinely granted in actions involving infringement and unfair competition.” *Benham Jewelry Corp. v. Aron Basha Corp.*, No. 97-CV-3841, 1997 U.S. Dist. LEXIS 15957, at \*58 (S.D.N.Y. Oct. 14, 1997). There are numerous examples from within this Circuit alone, in trademark cases involving conduct far less extreme than the sale of counterfeit HIV medication. *See, e.g., Philip Morris USA, Inc. v. Jackson*, 826 F. Supp. 2d 448, 450 (E.D.N.Y. 2011); *GAKM Res. LLC v. Jaylyn Sales, Inc.*, No. 08-CV-6030 (GEL) (THK), 2009 U.S. Dist. LEXIS 128595, at \*3 (S.D.N.Y. May 21, 2009); *Cartier Int’l B.V. v. Ben-Menachem*, No. 06-CV-3917 (RWS), 2007 U.S. Dist. LEXIS 95366, at \*1 (S.D.N.Y. Jan. 3, 2008); *Johnson & Johnson v. Champion Sales, Inc.*, No. 06-CV-5451 (SLT), Dkt. No. 3 (E.D.N.Y. Oct. 7, 2006); *ALCOA, Inc. v. ATM, Inc.*, No. 04-CV-5225 (DRH), Dkt. No. 9 (E.D.N.Y. Dec. 2, 2004); *Procter & Gamble Co. v. Xetal, Inc.*, No. 04-CV-2820 (DRH) (E.D.N.Y. July 7, 2004); *Chere Amie, Inc. v. Windstar Apparel Corp.*, 191 F. Supp. 2d 343, 344-45 (S.D.N.Y. 2001); *Hoffman-La Roche, Inc. v. Medisca, Inc.*, No. 99-CV-163, 1999 U.S. Dist. LEXIS 2380, at \*2 (N.D.N.Y. Mar. 3, 1999); *Tommy Hilfiger Licensing, Inc. v. Tee’s Ave., Inc.*, 924 F. Supp. 17, 18 (S.D.N.Y. 1996); *Francis S. Denney, Inc. v. I.S. Labs., Inc.*, 737 F. Supp.

247, 248 (S.D.N.Y. 1990); *Am. Cyanamid Co. v. Campagna Per Le Farmacie in Italia S.P.A.*, 678 F. Supp. 1049, 1055 (S.D.N.Y. 1987), *aff'd*, 847 F.2d 53 (2d Cir. 1988); *Playskool, Inc. v. Prod. Dev. Grp., Inc.*, 699 F. Supp. 1056 (E.D.N.Y. 1988).

Applying the four factors set forth in *Gidatex*, and based on the wealth of authority cited above, the Court should grant the limited expedited discovery that Gilead seeks. The first two factors are readily met: (1) plaintiffs have already demonstrated a likelihood of infringement, and (2) its business reputation and goodwill are being irreparably harmed. As for the third factor, discovery is a critical first step in exposing, and then shutting down, this unlawful activity. Expedited discovery will allow Gilead to prepare for, and the Court to conduct, a prompt preliminary injunction hearing. It will also enable Gilead to identify other persons and entities involved in the manufacture and distribution of the counterfeits. *See e.g., Twentieth Century Fox Film Corp.*, 749 F. Supp. at 475 (allowing discovery to proceed “on an expedited basis may very well lead to evidence of continuing infringement by [these] defendant[s] or others; it may also lead to the discovery of future plans to infringe or the discovery of additional infringing merchandise.”).

Finally, with respect to the fourth factor, the harm to Plaintiffs if discovery proceeds at the ordinary pace will far outweigh any conceivable harm to Defendants should this request for expedition be granted. The scope of discovery is narrow. *See Fed. Express Corp. v. Fed. Espresso, Inc.*, No. 97-CV-1219, 1997 U.S. Dist. LEXIS 19144, at \*5 (N.D.N.Y. Nov. 24, 1997) (“[T]he scope of permissible expedited discovery is limited to requests that are more narrowly ‘tailored to the time constraints under which both parties must proceed [and] to the specific issues that will have to be determined at the preliminary injunction hearing.’”). The proposed timetable calls for document production within three days of service of the request and

depositions on three days' notice. These documents should be at Defendants' disposal and Defendants will suffer little if any "injury" from having to produce them sooner rather than later. Conversely, without expedition, Gilead and the public will continue to be harmed by each and every additional sale of counterfeit medication.

#### **IV. GILEAD IS ENTITLED TO AN *EX PARTE* ORDER FREEZING DEFENDANTS' ASSETS**

As part of its efforts to immediately remove this counterfeit medication from the U.S. market, Gilead also seeks an asset freeze. Under the Lanham Act, Gilead is entitled to an accounting and disgorgement of Defendants' illicit profits from their sale and distribution of counterfeit Gilead medication that bears Gilead's trademarks. An *ex parte* asset freeze order will maintain the status quo, which includes preserving Gilead's ability to recoup the profits that Defendants earned from the sale of the counterfeit Gilead medication. This relief is not merely consistent with, but critical to, putting an immediate stop to Defendants' sale of counterfeits in the United States. Moreover, this relief is routinely granted in counterfeiting cases. The asset freeze order proposed here is functionally identical to an order that was recently granted by another court in an anti-counterfeiting case, which is attached as Exhibit 4 to the Potter Declaration.

##### **A. Legal Standard for Asset Freezes under the Lanham Act**

Where, as here, a plaintiff seeks lost profits and equitable remedies under the Lanham Act, 15 U.S.C. §§ 1116(a) and 1117, a federal court has the "inherent equitable powers to order preliminary relief, including an asset freeze, in order to assure the availability of permanent relief." *Levi Strauss & Co. v. Sunrise Int'l Trading, Inc.*, 51 F.3d 982, 987 (11th Cir. 1995); *see also Gucci Am., Inc. v. Bank of China*, 768 F.3d 122, 130, 132 (2d Cir. 2014) (stating the court is joining the three "sister circuits to have considered the issue" in holding that in trademark

infringement actions, “the district court ha[s] the inherent equitable authority to issue [an] Asset Freeze Injunction.”). Moreover, because “the Lanham Act authorizes the district court to grant [plaintiff] an accounting of [defendants’] profits as a form of final equitable relief, the district court ha[s] the inherent power to freeze [defendants’] assets in order to ensure the availability of that final relief.” *Reebok*, 970 F.2d at 559; *see also Balenciaga Am., Inc. v. Dollinger*, No. 10 Civ 2912 (LTS), 2010 U.S. Dist. LEXIS 107733, at \*22-24 (S.D.N.Y. Oct. 8, 2010) (collecting cases); *CSC Holdings, Inc. v. Redisi*, 309 F.3d 988, 996 (7th Cir. 2002) (“[S]ince the assets in question ... were profits of the [defendants] made by unlawfully stealing [the plaintiffs’] services, the freeze was appropriate and may remain in place pending final disposition of this case.”); *Motorola Inc. v. Abeckaser*, No. 07-cv-3963, 2009 U.S. Dist. LEXIS 40660, at \*8 (E.D.N.Y. May 14, 2009); *N. Face Apparel Corp. v. TC Fashions, Inc.*, No. 05-cv-9083, 2006 U.S. Dist. LEXIS 14226, at \*10 (S.D.N.Y. Mar. 30, 2006) (In counterfeiting cases, “[d]istrict courts have the ‘authority to freeze those assets which could [be] used to satisfy an equitable award of profits.’”). The purpose of such an order is “to preserve the possibility of an effective accounting of [the counterfeiter’s] profits and the return of the profits fraudulently obtained.” *Reebok*, 970 F.2d at 560. The requested injunctive relief will preserve the status quo and will also help secure the participation of the Defendants in this litigation.

Motions for an asset freeze under the Lanham Act are evaluated under the familiar standard for a preliminary injunction. *See Shamrock Power Sales, LLC v. Scherer*, No. 12-cv-8959, 2016 U.S. Dist. LEXIS 144773, at \*6 (S.D.N.Y. Oct. 18, 2016); *see also Lorillard Tobacco Co. v. Montrose Wholesale Candies & Sundries, Inc.*, No. 03-cv-4844, 2005 U.S. Dist. LEXIS 28917, at \*48 (N.D. Ill. Nov. 8, 2005).



**B. Gilead Has a Strong Likelihood of Success on the Merits**

As set forth above, *see pp. 7-10, supra*, the evidence leaves no room for doubt that the Defendants have sold counterfeit Gilead HIV medication, which is all that Gilead needs to establish to prevail on its strict-liability Lanham Act claims.

**C. Defendants Are Likely to Dissipate Assets, and Gilead Will Suffer Additional Irreparable Harm If Their Assets Are Not Frozen**

Counterfeiters like Defendants make their living by secrets and subterfuge, and therefore are likely to “hide their allegedly ill-gotten funds” if their assets are not frozen. *Reebok*, 970 F.2d at 563; *accord Chanel, Inc. v. Classic-Bag-Shop*, No. 19-cv-60492, 2019 U.S. Dist. LEXIS 42688, at \*10 (S.D. Fla. Mar. 14, 2019) (“In light of the inherently deceptive nature of the counterfeiting business ... Plaintiff has good reason to believe Defendants will hide or transfer their ill-gotten assets beyond the jurisdiction of this Court unless those assets are restrained.”). When engaged in the practice of selling fake HIV medication with an entirely different drug inside, serious civil and criminal exposure is a given. Each Defendant operates outside of and in violation of the law while doing business in a heavily regulated industry, and each depends on fraud and subterfuge to sell its highly illegal product in U.S. commerce. The record evidence strongly supports the conclusion that the Defendants will conceal or dissipate its illegal profits when given the chance.

**1. Safe Chain and Its Founders, the Boyds**

Gilead has set forth above, in detail, Safe Chain’s numerous schemes, lies, and evasions in service of its continuing willful sale of counterfeit HIV medications. In summary:

- Safe Chain purchased from recently opened, unlicensed, fly-by-night counterfeiters, and then falsely affirmed on every single pedigree provided to its pharmacy customers that it purchased the drugs from an “authorized trading partner.”

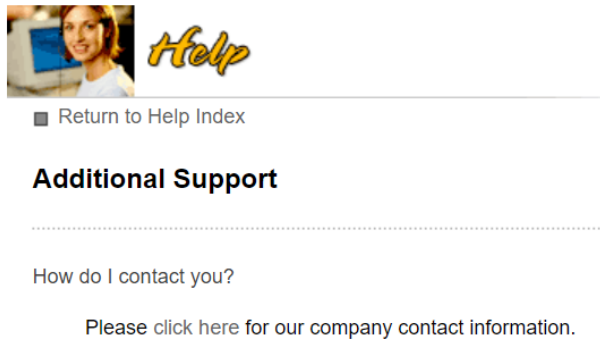
- Safe Chain not only passed on obviously fraudulent pedigrees to its customers, but itself created new false pedigrees to conceal the fact that it was sourcing from counterfeiters.
- Safe Chain conspired with Defendant Brosius, the indicted healthcare fraudster who founded Worldwide Pharma after being ousted from his pharmacy, to both source and sell the counterfeits.
- Safe Chain worked with Worldwide Pharma, bypassing its own compliance director, to orchestrate the “pass-through” scam to buy counterfeits from Rapids Tex while pretending to source from a legitimate, licensed supplier.
- Safe Chain attempted to conceal reported counterfeits from Gilead, and then lied about it when Gilead discovered the counterfeits on its own.
- Safe Chain continued buying thousands of illicit bottles of Gilead medication after being informed that its suppliers had sold counterfeits to Safe Chain.
- Safe Chain lied to Gilead, and used outside counsel to communicate the lie, that Safe Chain had personally verified that its new supplier was buying directly from an authorized counsel.
- Safe Chain tried to use its lie about its new supplier to fraudulently convince Gilead to enter a general release and withdraw a pending federal subpoena.

The Safe Chain Defendants have no compunction about selling dangerous HIV medications or lying to Gilead and Gilead’s attorneys to keep its illegal trade going. *See, e.g., Dong v. Miller*, No. 16-cv-5836, 2018 U.S. Dist. LEXIS 48506, at \*34-35 (E.D.N.Y. Mar. 23, 2018) (granting asset freeze where defendants refused to comply with subpoenas and falsified documents to conceal their unlawful transactions). They cannot be trusted, and they have every incentive to hide their assets, just as they hid their counterfeiting.

## **2. Worldwide Pharma and Brosius**

The same is true for Worldwide Pharma and its principal, Brosius, who as set forth above conspired with Safe Chain on all aspects of the purchase, advertising, and sale of counterfeits. The depth of Worldwide Pharma’s involvement in Safe Chain’s counterfeiting leaves little room for doubt that it was privy to, and involved in, Worldwide Pharma’s fraudulent schemes.

Moreover, Worldwide Pharma and Brosius have no established physical presence. Gilead's investigators have been unable to locate Brosius's current residence using public databases. Coleman Decl. ¶ 22. Wherever it may be, Brosius appears to run Worldwide Pharma from his home: the company has no offices, has no known tangible assets, and uses a mailbox at a UPS Store when listing its address in government filings. *Id.* This is confirmed by Worldwide Pharma's website, pharmasales.com. On its FAQ page, Worldwide Pharma provides the following:<sup>18</sup>



Yet clicking on the link for “company contact information” simply takes the user to a generic “about us” page with no contact information whatsoever:<sup>19</sup>

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<sup>18</sup> [https://www.pharmasales.com/help\\_answer.asp?ID=17#46](https://www.pharmasales.com/help_answer.asp?ID=17#46)

<sup>19</sup> <https://www.pharmasales.com/aboutus.asp>



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Best regards,  
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In short, Brosius and Worldwide Pharma appear to be making a concerted effort not to be found.

It would be exceedingly easy for them to dissipate assets if given the opportunity.

Moreover, the threat of criminal and civil liability are obviously not deterrents for Brosius and Worldwide Pharma. Brosius and Worldwide Pharma's predecessor are under indictment for running a massive healthcare fraud scheme, including Brosius's use of his company to find and recruit dishonest physicians to effectuate the fraud. Coleman Decl. Ex. 9. And while under indictment, Brosius and Worldwide Pharma conspired with Safe Chain to orchestrate the "pass-through" scam, with Mr. Unlimited and Rapids Tex.

### **3. Boulevard and Shukurov**

Boulevard and its owner, Shukurov, are precisely the type of unregistered and unlicensed fly-by-night suppliers that were necessary to Safe Chain's counterfeiting. Without the requisite distributor's license, they willfully sold counterfeits to Safe Chain and created fraudulent pedigrees to facilitate that sale. *See, e.g., Shaoxing Bon Textiles Co. v. 4-U Performance Grp. LLC*, No. 16-cv-6085, 2017 U.S. Dist. LEXIS 20785, at \*9-10 (S.D.N.Y. Feb. 6, 2017) (finding irreparable harm where defendants sought to conceal unauthorized sales by selling through a third-party diverter and failed to report sales to their factoring partner). They then abandoned their offices when their counterfeiting came to light. Illegal and operating out of a small condominium office space, Shukurov's operation appears to have been designed to be packed up

and hidden at the first hint of trouble – which is precisely what happened when Boulevard’s counterfeiting came to light. Having abandoned their offices and lost Safe Chain as a major customer for its counterfeits, Shukurov and Boulevard, absent an asset freeze, would be expected to dissipate their ill-gotten gains. *See id.* at \*9 (irreparable harm established where defendant is or imminently will be insolvent); *Netwolves Corp. v. Sullivan*, No. 00-cv-8943, 2001 U.S. Dist. LEXIS 5905, at\*35-37 (S.D.N.Y. May 8, 2001) (same).

All of this evidence strongly indicates that the Defendants “may hide their allegedly ill-gotten funds if their assets are not frozen.” *Lorillard Tobacco Co.*, 2005 U.S. Dist. LEXIS 28917, at \*57 (quoting *Reebok*, 970 F.2d at 563); *see id.* at \*56 (“In this case, the Lanham Act provides [Plaintiffs] with the equitable remedy of recovering [Defendants’] profits. In such cases, courts have generally concluded that an asset freeze is appropriate to ensure that permanent equitable relief will be possible.” (quoting *Levi Strauss & Co.*, 51 F.3d at 987; *Reebok*, 970 F.2d at 559)).

#### **D. The Balance of the Equities Strongly Favors Gilead**

The balance of harms also heavily weighs in favor of an asset freeze. The evidence shows that Defendants knowingly sold counterfeit medications in violation of the Lanham Act. Any harm an asset freeze may cause to Defendants was “brought upon themselves with their tactics of deception and underhandedness.” *Lorillard Tobacco Co.*, 2005 U.S. Dist. LEXIS 28917, at \*58. By comparison, the harm to Gilead’s trademarks and goodwill, as well as the harm to unsuspecting patients, caused by Defendants’ actions is clear.

To the extent that the Defendants can demonstrate – contrary to the overwhelming evidence – that their assets are not the fruits of their counterfeiting, they can make such a showing to the Court and have the freeze lifted or amended. *See Balenciaga Am*, 2010 U.S. Dist. LEXIS 107733, at \*24-26. Defendants can also move to have sufficient funds released to pay

their lawyers and other necessary expenses. In fact, undersigned counsel has frequently been able to reach accord on such issues with parties affected by an asset freeze without the need for motion practice or court intervention. Gilead, on the other hand, will have no recourse if the Defendants dissipate their assets. *See Dong*, 2018 U.S. Dist. LEXIS 48506, at \*41-42. Once hidden or removed from the Court's reach, there is very little that can be done to recover a counterfeiter's assets.

**E. The Public Interest Is Served by an Asset Freeze**

Each of the Defendants has continued to sell dangerous counterfeit HIV medications *after* being caught. An asset freeze is in the public interest because it will help secure the Defendants' participation in this lawsuit and ensure they do not continue to purchase and sell counterfeits during the course of litigation. *See Std. & Poor's Corp. v. Commodity Exch., Inc.*, 683 F.2d 704, 711 (2d Cir. 1982) (“[A] court of equity ... may go much further both to give or to withhold relief in furtherance of the public interest than where only private interests are involved.”). There will be no harm to the public from the asset freeze, as there is no shortage of legitimate distributors who can deliver authentic Gilead medication to any pharmacy in the nation.

**F. The Asset Freeze Should Be Global in Scope**

Notably, the Court's authority to freeze assets is not limited to assets within this District, nor even to assets within the United States. *See, e.g., Citronelle-Mobile Gathering, Inc. v. Watkins*, 943 F.2d 1297, 1301 (11th Cir. 1991) (upholding district court order directing “banks or financial institutions wherever located to freeze the judgment debtors' assets.” (internal quotation marks omitted)); *Iron Maiden Holdings Ltd. v. Partnerships & Unincorporated Associations Identified on Schedule “A”*, No. 1:18-cv-1098, 2018 WL 2077732, at \*4 (N.D. Ill. Mar. 6, 2018) (issuing asset restraining order on “[a]ny banks, savings and loan associations, payment processors or other financial institutions, including . . . PayPal, . . . for any Defendant”); *see also*

*United States v. First Nat'l City Bank*, 379 U.S. 378, 384 (1965) (“Once personal jurisdiction of a party is obtained, [a district court] has authority to order it to ‘freeze’ property under its control, whether the property be within or without the United States.”); *Balenciaga*, 2010 U.S. Dist. LEXIS 107733, at \*25-26 (same).

Similarly, this Court is armed with authority under the All Writs Act, 28 U.S.C. § 1651, to issue such orders requiring the cooperation of banks and other non-parties that may have physical custody of defendants’ assets or have provided payment services to any of the Defendants. *See Thorogood v. Sears, Roebuck & Co.*, 678 F.3d 546, 548 (7th Cir. 2012) (The All Writs Act “has been interpreted to empower a federal court ‘to issue such commands ... as may be necessary or appropriate to effectuate and prevent the frustration of orders it has previously issued in its exercise of jurisdiction otherwise obtained.’ This power ‘extends, under appropriate circumstances, to persons who, though not parties to the original action or engaged in wrongdoing, are in a position to frustrate the implementation of a court order or the proper administration of justice, and encompasses even those who have not taken any affirmative action to hinder justice.’” (citation omitted) (alteration in original) (quoting *United States v. New York Tel. Co.*, 434 U.S. 159, 172, 174 (1977)); *Burr & Forman v. Blair*, 470 F.3d 1019, 1026-27 (11th Cir. 2006) (“The power to issue writs under the Act is not circumscribed by the identity of the parties immediately before the court; at the court’s discretion, writs may be issued to third parties who are in a position to frustrate a court’s administration of its jurisdiction.” (citing *United States v. New York Tel. Co.*, 434 U.S. 159, 174 (1977)); *In re Uranium Antitrust Litig.*, 617 F.2d 1248, 1259 (7th Cir. 1979) (“We also find support for the district court’s authority to enter these [asset freeze] injunctions in the All Writs Act.”). Accordingly, Gilead respectfully submits that the asset freeze order freeze all assets of Defendants, wherever and in whomever’s possession they

may be found, and issue such subsequent and additional injunctive orders against non-parties to this action as may be necessary to enable Gilead to fully enforce this asset freeze order.

**G. The Asset Freeze Should Be Issued *Ex Parte***

Finally, in order to ensure that the accounting and lost profits sought by Gilead are available at the conclusion of this action, that Gilead's right to a full equitable accounting of Defendants' profits is not impaired, and that Defendants participate in this action, Gilead respectfully submits that the order be issued *ex parte*. See *Columbia Pictures Indus., Inc. v. Jasso*, 927 F. Supp. 1075, 1077 (N.D. Ill. 1996) (relying on *In re Vuitton Et Fils S.A.*, 606 F.2d 1, 4-5 (2d Cir. 1979), "and its progeny," to conclude that "proceedings against those who deliberately traffic in infringing merchandise are often rendered useless if notice is given to the infringers"). The Defendants here are uniquely well-positioned to easily hide or dispose of their assets if given prior notice, which would render an accounting by Gilead meaningless.

**CONCLUSION**

For the reasons stated above, the Court should grant Gilead's motion for an *ex parte* seizure order, a temporary restraining order (to be followed by a preliminary injunction), an expedited discovery order, and an asset freeze order, and should award any other and further relief that the Court may deem just and proper. Proposed orders for the requested relief are being filed simultaneously herewith.



Dated: July 22, 2021

Respectfully submitted,



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